

EXHIBIT C

2 IN THE COURT OF COMMON PLEAS
3 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
4 CIVIL TRIAL DIVISION
5 ---
6 MARGARET ENGLEMAN :
7 VS. : MARCH TERM, 2014
8 ETHICON, INC., ET AL. : No. 05384
9 ---
10 THURSDAY, APRIL 13, 2017
11 AFTERNOON SESSION
12 ---
13 TRIAL
14 ---
15 COURTROOM 436
16 CITY HALL
17 PHILADELPHIA, PENNSYLVANIA
18 ---
19 B E F O R E: THE HONORABLE ANN M. BUTCHART, J.
20 AND A JURY
21
22
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24
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COLLOQUY

2 THE COURT: Good afternoon. If
3 defense would put the form of the objection
4 on the record and please be seated. Thank
5 you. I believe that the issue was
6 Dr. Rosenzweig was about to offer testimony
7 with regard to an article that has been
8 identified as P-2557 in plaintiff's
9 evidence binder.

10 Do you want to proceed with the nature
11 of your objection?

12 MR. CAMPBELL: The objection, Your
13 Honor, is based upon the Pennsylvania Rule
14 of Evidence and the Aldridge case, and it's
15 Pennsylvania Rule of Evidence 803(18).

16 On direct examination, the rule seems
17 quite clear that an expert can't bolster
18 his or her opinion by making reference to
19 the content of a learned treatise. The
20 expert is, as I understand the rule and the
21 interpreting cases, is entitled to identify
22 the basis of his or her opinion to the
23 extent it is a learned treatise. They can
24 state the title of it, the author of it,
25 and subject matter.

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2 And, after that, I believe one of the
3 cases says neither counsel may ask an
4 expert witness to read a learned treatise
5 to the jury under the guise of a
6 permissible purpose, and there is no excuse
7 for this improper approach. That's out of
8 the Bernstein volume. So that would be the
9 basis of the objection. It's not permitted
10 by the rule and it's hearsay.

11 THE COURT: Do you have a response?

12 MR. ANDERSON: No more than I already
13 had this morning through my arguments, Your
14 Honor, so I stand on that.

15 THE COURT: We're going to overrule
16 this objection. A close reading of
17 Aldridge and my learned colleague Mark
18 Bernstein's treatise indicates to me that
19 the Court has some leeway in this.

20 I have, however, spoken to counsel and
21 advised that any testimony proffered by
22 Dr. Rosenzweig with regards to this
23 particular article will be brief and will
24 not go beyond the confines that Aldridge
25 has expressed. He may state the basis of

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2 his opinion and he may testify briefly as
3 to how his opinion was formed by this.
4 Thank you.

5 MR. CAMPBELL: Understood, Your Honor.
6 Thank you.

7 MR. ANDERSON: Thank you.

8 THE COURT OFFICER: All rise as the
9 jury enters the room.
10 (The jury enters the courtroom at
11 1:13 p.m.)

12 THE COURT: Please be seated. Welcome
13 back. Dr. Rosenzweig is still on the
14 stand.

15 MR. ANDERSON: Thank you, Your Honor.

16 - - -

17 DIRECT EXAMINATION
18 - - -

19 BY MR. ANDERSON:
20 Q. Referring now to tab 6, P-2557, do you have
21 that in front of you?
22 A. Yes.
23 Q. Is this something that you reviewed in
24 forming your opinions in this case, Dr. Rosenzweig?
25 A. Yes.

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2 Q. Did you rely upon it in forming your
3 opinions?
4 A. Yes.
5 Q. Is it significant to your opinions?
6 A. Yes.
7 Q. Is this an authoritative text?
8 A. Yes.
9 Q. Okay. If you would just briefly tell us
10 what this article is entitled and what year it was
11 and the authors?
12 A. This is a research paper by Dr. Susan Ross
13 from Canada. It was published in 2014. The title
14 is: Single incision TVT Secur versus retropubic
15 tension-free tape for the management of stress
16 urinary incontinence in women: A randomized clinical
17 trial.
18 Q. Briefly, how did this inform your opinions
19 in this case?
20 A. The study was designed to start in 2007.
21 It was concluded in 2011. What they wanted to do is
22 get 300 women in the study. They could only get 70
23 women in the study and they stopped the study.
24 Q. How does that inform your opinions or
25 support the opinions that you've offered here this

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2 morning?
3 A. Well, one of the difficulties that they had
4 in getting patients is that the doctors did not have
5 confidence in the TVT Secur.
6 Q. Thank you very much. Now, let's move on,
7 if we could, to tab 7, and this is P-2531.
8 Is this a document that you reviewed and
9 relied upon in forming your opinions in this case?
10 A. Yes, I did.
11 Q. Is it significant to your opinions?
12 A. Yes, it is.
13 Q. Is it authoritative?
14 A. Yes.
15 Q. Please briefly discuss what this paper is
16 and how it informed your opinions, briefly?
17 A. This is a position statement from the
18 National Institute for Health and Clinical Education,
19 which is a group in England that looks at medical
20 issues. This came out in 2008. And what the
21 position statement states is that the short,
22 single-incision slings should only be used in
23 research purposes or as part of a large registry.
24 Q. How does that inform the opinions that
25 you've already offered here this morning?

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2 of the document, let me ask you, it says: Laser-cut
3 and machine-cut TVT meshes.
4 Do you see that?
5 A. Yes.
6 Q. Please briefly explain to the jury the
7 difference between a laser-cut mesh and a
8 mechanical-cut mesh.
9 A. Prior to the design of the TVT Secur, the
10 mesh, the full-length mesh that had 18 centimeters in
11 the body, was cut with a guillotine or a machine.
12 The Secur, which is only 8 centimeters, was now cut
13 with a laser.
14 Q. And in terms of the physical
15 characteristics of the mesh, what, if anything,
16 according to your review of the records and the
17 depositions in this case, what, if anything, does
18 laser-cutting the mesh, the edges of the mesh, do to
19 the mesh?
20 A. What this document shows, which is an
21 internal study that was done by Ethicon, is that the
22 mesh became three times stiffer by using a laser to
23 cut the mesh into 1 centimeter strips than using the
24 guillotine to mechanically cut the mesh.
25 Q. Is this what we're seeing on the screen

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10
2 A. That this device needed to have been
3 studied prior to launch so that any of the defects of
4 the device would have been known prior to launch and
5 doctors would have known about it.
6 Q. Thank you, Doctor. Moving to tab 8,
7 Exhibit P-0732, is this a document that you reviewed
8 and relied upon in coming to your opinions in this
9 case?
10 A. Yes.
11 Q. And is it significant to your opinions?
12 A. Yes.
13 Q. Please explain to the jury what P-0732 is.
14 A. This is an internal Ethicon document. This
15 is from a comparison of the stiffness of the
16 laser-cut mesh versus the way the mesh was cut
17 before, which is mechanical-cut mesh.
18 Q. Just one second. Let me ask you this. I
19 apologize. I forgot to ask.
20 Who are the authors and recipients here?
21 A. This is from Becky Leibowitz, a scientist
22 at Ethicon, to Paul Parisi and Dan Smith. Dan Smith
23 is an engineer. He is one of the co-patent holders
24 of the TVT Secur.
25 Q. Now, before we get into the actual content

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2 here in this December 14, 2004 e-mail?
3 A. Correct.
4 Q. Thank you. Moving on to tab 9, Plaintiff's
5 P-1676, is this something that you reviewed and
6 relied upon in forming your opinions in this case?
7 A. Correct.
8 Q. Is it significant to your opinions?
9 A. Yes.
10 Q. Can you please explain what we have here?
11 A. This is an e-mail from Dan Smith, again,
12 engineer and one of the co-patent holders on the
13 Secur device. It's from November 13, 2008.
14 THE COURT: One second, please.
15 MR. ANDERSON: Oh, wait. I think you
16 have the wrong one, P-1676.
17 THE WITNESS: Yes. Page 4 describes
18 the author of this is Dan Smith and the
19 date.
20 THE COURT: Just a second.
21 BY MR. ANDERSON:
22 Q. You said internal e-mail. Did you mean
23 internal document? Maybe that's where we got lost.
24 A. It was part of an e-mail, but I guess it's
25 better to say that it was an internal document.

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2 Q. Explain why this internal Ethicon document
3 forms your opinions in this case.

4 A. Dan Smith is discussing the rigidity and
5 stiffness of short laser-cut mesh and states that it
6 is more stiff and rigid than the full-length
7 mechanical-cut mesh.

8 Q. How does that inform or instruct the
9 opinions you've already provided to the jury today?

10 A. That one of the defects of the mesh in the
11 8-centimeter short TVT Secur mesh is stiffer.

12 Q. Going to tab 10, Plaintiff's P-2563, is
13 this something you reviewed and relied upon in
14 forming your opinions in this case?

15 A. Yes.

16 Q. Is it significant to your opinions in this
17 case?

18 A. Yes.

19 Q. Please identify what the document is and
20 then tell us why it informs your opinions.

21 A. This is an e-mail from Michelle Irvin, who
22 is a sales representative from Illinois on the 9th of
23 December 2010. She states that stiffer mesh leads to
24 more tissue breakdown, tissue degradation, and more
25 complications.

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2 Q. How does that inform the opinions with
3 regard to the Secur device?

4 A. That Ethicon had scientific knowledge that
5 a stiffer mesh like the short mesh in the TVT Secur
6 was stiffer. It leads to more risk to the patient.
7 One of those risks and one of those harms is the
8 breakdown of tissue, which we described as far as
9 erosion, and more complications.

10 Q. Have you reviewed internal documents
11 regarding Ethicon's relationship between stiff and
12 rigid mesh in the vagina and injuries to women?

13 A. Yes.

14 Q. Let me ask you if you will turn to tab 11,
15 Exhibit P-705.

16 Did you use this to form your opinions in
17 this case?

18 A. Yes, I did.

19 Q. Significant?

20 A. Yes.

21 Q. Can you please tell us what this is?

22 A. This is another internal document from
23 Jürgen Trzewik, a scientist and engineer at Ethicon,
24 who describes on the last page of the document that
25 mesh softness is something that doctors want for

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1 their patients, and it enhances the biological -- the
2 way that the mesh interacts with the body. So a
3 stiffer mesh is going to have more of a negative
4 impact on a woman's body than the softer mesh.

5 Q. How does that inform or instruct your
6 opinions as to whether or not the mesh in the TVT
7 Secur is effective or not?

8 A. This shows that the shorter stiffer mesh in
9 the TVT Secur is defective, and the harm is damage to
10 the delicate tissue of a vagina.

11 Q. With regard to scar plating that you
12 mentioned earlier to the jury, does this instruct or
13 inform your opinions as to whether scar plating in
14 the tissue of the Secur can cause injury to women?

15 A. Yes.

16 Q. How so?

17 A. This describes that when the holes in the
18 mesh are small, it increases the risk of scar
19 plating. Scar plating makes the mesh stiffer, and,
20 as we said, stiffness leads to more harm in women.

21 Q. Tab 12, please, Plaintiff's P-1102, is this
22 something that you reviewed in forming your opinions
23 in this case?

24 A. Yes.

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1 Q. Is it significant to your opinions?

2 A. Yes, it is.

3 Q. Okay. Please identify the document.

4 A. This is an interview with a key opinion
5 leader, that's what KOL means, key opinion leader.
6 In this case it's Dr. Carl Nilsson.

7 Q. Sorry, 1128.

8 THE COURT: What number again, please,
9 Counsel?

10 MR. ANDERSON: Sorry, Your Honor.
11 It's tab 12, P-1128.

12 THE COURT: Thank you.

13 MR. ANDERSON: Thank you, Your Honor.

14 THE WITNESS: Internal Ethicon
15 document. It is a transcript of an
16 interview with Dr. Carl Nilsson. Carl
17 Nilsson is a very well-known pelvic
18 surgeon. He's also one of the co-inventors
19 of the TVT Retropubic. The date of this is
20 6/18/2008.

21 BY MR. ANDERSON:

22 Q. What part of it would be instructive to
23 your opinions in this case, Doctor?

24 A. First is the second paragraph where
25

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<p>17</p> <p>2 Dr. Nilsson is describing that there must be clinical 3 data. Doctors need clinical data on a device in 4 order to allow them to use this in a patient. Later 5 on it's described that Dr. Nilsson told the 6 interviewer that the mini sling, the TVT Secur, would 7 never work. 8 Q. Say that again. I'm sorry. 9 A. That the TVT mini sling will never work, 10 and one of the reasons is that the laser-cut mesh is 11 too stiff. 12 Q. And if we could go down to under "mesh 13 properties" also by Carl Nilsson. 14 THE COURT: What page are we on? 15 MR. ANDERSON: We are on the second 16 page, Your Honor, and it's about just over 17 halfway down you'll see CN and then "mesh 18 properties." 19 THE COURT: Thank you. 20 MR. ANDERSON: Thank you. Sorry. I 21 went too fast. If you could highlight 22 that. 23 BY MR. ANDERSON: 24 Q. Does this instruct your opinions? How does 25 this support any of your opinions regarding the Secur</p> <p>SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>	<p>18</p> <p>2 mesh? 3 A. That one of the defects of the Secur mesh 4 is that it is too stiff, and the stiffness will 5 impact its ability to treat a woman's condition, in 6 this case, stress incontinence, which means that she 7 will have a recurrence of her stress incontinence and 8 require another surgical procedure to treat that. 9 Q. Thank you, Doctor. Turning to Plaintiff's 10 P-1102, that is tab 13, Your Honor. 11 Is this a document that you also relied 12 upon in forming your opinions? 13 A. Yes, it is. 14 Q. Significant to your opinions? 15 A. Yes, it is. 16 Q. Please identify the document and then tell 17 the jury why this supports your opinions, please. 18 A. Yes. This is an e-mail from two Ethicon 19 employees. It's describing an e-mail from a 20 Dr. Neuman, and Dr. Neuman is a well-regarded pelvic 21 surgeon. He's a scientist. He is also an Ethicon 22 consultant. He has studied the TVT Secur 23 extensively. If we go to the second page, bullet 24 point 5, he is describing that -- 25 Q. Second page, bullet point 5, let's slow</p> <p>SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>
<p>19</p> <p>1 DIRECT - ROSENZWEIG 2 down a little bit and let everyone catch up to us. 3 You and I are off to the races. 4 A. I wanted to get everybody home for the long 5 weekend. 6 Q. Yes. All right. Let's do it as slowly as 7 we can, unfortunately. 8 All right. Now, we're there. Tell us why 9 this instructs your opinion. 10 A. What Dr. Neuman, who, again, is a very 11 well-regarded pelvic surgeon, very knowledgeable, has 12 used the TVT Secur, is stating that the stiffness, 13 which is the defect of the short stiff TVT Secur, the 14 harm that causes in women is vaginal pain and erosion 15 of the tape through the vagina. 16 Q. And this "too many undesired tape removals 17 are reported," how does that instruct your opinions, 18 if at all? 19 A. One of the unfortunate consequences of the 20 complication, such as a tape protrusion, is that it 21 would require surgery to fix that. 22 Q. Thank you, Doctor. Do you find that 23 opinion to relate to the TVT Secur mesh? 24 A. Correct. 25 Q. Does that further supplement your opinions</p> <p>SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>	<p>20</p> <p>1 DIRECT - ROSENZWEIG 2 with regard to the stiffness of the mesh? 3 A. Correct. 4 Q. Turning now, please, to tab 14, P-2564, is 5 this something that you reviewed and relied upon in 6 forming your opinions? 7 A. Correct. 8 Q. And is that significant to your opinions? 9 A. Correct. 10 Q. If you'll look with me on page 2 to the 11 conclusions -- 12 MR. CAMPBELL: Excuse me. 13 THE COURT: I don't believe this 14 should go up on your screen. 15 MR. ANDERSON: It's an internal 16 document, Your Honor. It is a study. 17 (Sidebar discussion as follows:) 18 MR. ANDERSON: I apologize. I 19 apologize. Once you pointed it out to me, 20 I realize, saw the dates and saw -- 21 THE COURT: What do you want to do? 22 MR. ANDERSON: I'll pull it off the 23 screen. Thank you. 24 (End of sidebar discussion.) 25 THE COURT: Members of the jury, this</p> <p>SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>

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2 entire trial is fueled by coffee. Some

3 people have to watch their intake at lunch.

4 It's done so that as much information as

5 you need can be imparted to you in the most

6 efficient way.

7 Okay. Please resume, Mr. Anderson.

8 MR. ANDERSON: Thank you, Your Honor.

9 THE COURT: Do you withdraw that last

10 exhibit?

11 MR. ANDERSON: We will withdraw it

12 from publication, yes, Your Honor.

13 THE COURT: Thank you.

14 BY MR. ANDERSON:

15 Q. Is this an authoritative text?

16 A. Yes, it is.

17 Q. Okay. Briefly, how did this form your

18 opinions in this case?

19 A. This is an article that describes the

20 effect of stiff mesh on the tissue that surrounds it.

21 They describe a concept called stress shielding. The

22 best way to describe that is when you put a cast on

23 your arm. Your fingers are still moving, your

24 muscles are still moving, but six months later or six

25 weeks later, when the cast comes off --

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1 relied upon in coming to your opinions in this case?

2 A. Correct.

3 Q. And does it support your opinions?

4 A. Correct.

5 Q. And is this an authoritative text?

6 A. Yes.

7 Q. Briefly describe what the document is, and

8 then we'll talk about how it informs your opinions.

9 A. Yes. This is another document that talks

10 about the stiffness of the mesh and the negative

11 effect it has on the vagina, that it causes the

12 vagina to thin out, it causes the muscles of the

13 urethra not to work as well.

14 Q. What is the problem when they thin out and

15 the urethra doesn't work as well?

16 A. Well, when the vagina thins out, that can

17 lead to the mesh protruding through the thinned-out

18 vagina, and it could lead to an erosion.

19 Q. Do you have an opinion as to whether or not

20 the TVT Secur mesh acts in that fashion?

21 A. Yes.

22 Q. What is that opinion?

23 A. That the TVT Secur mesh, because it's

24 stiffer and harder, causes deleterious effects on the

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2 MR. CAMPBELL: Excuse me, Your Honor.

3 It's beyond the permitted scope of the use

4 of this type of document.

5 THE COURT: If you could direct your

6 witness to summarize briefly.

7 MR. ANDERSON: He mentioned stress

8 shielding.

9 May I offer what stress shielding is?

10 THE COURT: Very briefly.

11 BY MR. ANDERSON:

12 Q. Briefly, what is stress shielding?

13 A. Stress shielding is when you put something

14 stiffer around the tissue. The tissue thins out and

15 has a negative response. It thins. It becomes less

16 pliable.

17 Q. How does this article address that,

18 quickly?

19 A. This study looked at the stress shielding

20 in the vagina as a deleterious effect on the vaginal

21 tissue and the muscle around the vaginal tissue like

22 the urethra.

23 Q. Thank you. Plaintiff's 2499, tab 15, Your

24 Honor.

25 Is this an article that you reviewed and

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1 vagina, meaning the vagina is going to thin out over

2 time. It will lead to more erosion, which is the

3 harm created by that defect.

4 Q. Doctor, if you could turn to tab 17, which

5 is P-2309, is this something that you reviewed and

6 relied upon in forming your opinions in this case?

7 A. Yes.

8 Q. And is it an authoritative text?

9 A. Yes.

10 Q. Is it significant to your opinions in this

11 case?

12 A. Yes.

13 Q. Briefly describe what the article is and

14 how it informs your opinions.

15 A. This is a randomized control trial

16 comparing TVT Secur to a full-length sling. They

17 found that there was more pain with intercourse with

18 a TVT Secur, and the authors found that it was the

19 stiffness and rigidity of the mesh that was

20 responsible for the pain with intercourse.

21 Q. Thank you. Do you have an opinion as to

22 whether or not the stiffness and rigidity of the TVT

23 Secur mesh would have the results that we just saw in

24 2309?

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2 A. Yes.
3 Q. What is that opinion?
4 A. That the stiffness and rigidity of the TVT
5 Secur mesh, that is the characteristic that is
6 defective, the harm it would cause to a woman is pain
7 with intercourse.
8 Q. Showing you Plaintiff's tab 18, Exhibit
9 P-0292, is this an article -- I'm sorry. Is this a
10 document that you reviewed in forming your opinions
11 in this case?
12 A. Yes, it is.
13 Q. Is it significant to your opinions?
14 A. Yes, it is.
15 Q. Is it significant to your opinions
16 regarding design defect of the Secur mesh?
17 A. Yes, it is.
18 Q. Could you please tell the jury what we are
19 looking at?
20 A. This is an e-mail from Dr. David Robinson.
21 Dr. Robinson is a pelvic surgeon. At the time he was
22 also the medical director for Ethicon in the United
23 States. He's sending this to a colleague and
24 describes that the increased rigidity, stiffness of
25 the mesh, causes the harm to women of impaired sexual

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2 function. Impaired sexual function means pain with
3 intercourse.
4 Q. Anything further?
5 A. And mesh that they make in the future
6 should be less stiff.
7 Q. If you would please now go to tab 20, and
8 that is Plaintiff's P-2561, have you reviewed this
9 document?
10 A. Yes.
11 Q. Is it a scientific article that is
12 authoritative?
13 A. Yes.
14 Q. Does it form the basis of your opinions and
15 significant to your opinions?
16 A. Yes.
17 Q. First of all, just tell us the authors and
18 the journal and what the title is.
19 A. The author is Krofta. The journal is the
20 International Urogynecological journal. The date of
21 publication is --
22 Q. Slow down just a little bit.
23 A. Date of publication is 2010. The title is:
24 TVT-S for surgical treatment of stress urinary
25 incontinence: Prospective trial, one-year follow-up.

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1 DIRECT - ROSENZWEIG
2 Q. Now, briefly tell us how this informs your
3 opinions in this case.
4 A. They found that at one year, 50 percent of
5 women had failed.
6 Q. What do you mean by "failed"?
7 A. Meaning the device did not work to treat
8 their stress urinary incontinence. They were still
9 leaking urine when they cough or sneeze.
10 Q. Does this article further support your
11 opinions regarding the defective nature of the TVT
12 Secur device?
13 A. Yes. What they conclude is that the
14 anchoring system, the fleece ends of the mesh, did
15 not hold, and, therefore, the device failed.
16 MR. CAMPBELL: Excuse me, Your Honor.
17 I object again. Going beyond the scope of
18 Your Honor's ruling.
19 THE COURT: I'm going to sustain the
20 objection. I'm certain that this is the
21 last opinion on this subject that he's
22 giving.
23 Go ahead. The anchoring system. You
24 can continue your sentence.
25 THE WITNESS: Yes, did not hold.

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1 DIRECT - ROSENZWEIG
2 THE COURT: Thank you.
3 MR. ANDERSON: Thank you.
4 BY MR. ANDERSON:
5 Q. Showing you now Plaintiff's P-2320, tab 21,
6 is this an article that you reviewed and relied upon
7 in forming your opinions in this case?
8 A. Yes.
9 Q. Is it significant to your opinions?
10 A. Yes.
11 Q. Is this an authoritative text?
12 A. Yes.
13 Q. Please describe, first of all, just what
14 the title is and the authors.
15 A. Yes. This is from Dr. Abdel-Fattah. It
16 was published in 2011 in the European Urology
17 journal. The title is: Single-incision mini-slits
18 versus standard midurethral slings in surgical
19 management of female stress urinary incontinence: A
20 meta-analysis of effectiveness and complications.
21 Q. Before we get into why this is significant
22 to your opinions, if at all, what is a meta-analysis?
23 A. A meta-analysis is a research study where,
24 instead of looking at individual patients, you're
25 looking at other research papers, taking the best

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2 quality ones, analyzing them, taking the data out,
 3 and then reporting that.
 4 Q. Over how many years was this meta-analysis?
 5 A. The meta-analysis was from 1996 through
 6 2011.
 7 Q. And how does this inform your opinions at
 8 all in this case?
 9 A. This found that there was a lower success
 10 rate for the mini slings, and the TVT Secur in
 11 specific, due to the fleece holding mechanism.
 12 Q. Does that instruct and inform and support
 13 your opinions that you already offered to the jury
 14 today?
 15 A. Yes.
 16 Q. Showing you now a tab 22, Plaintiff's
 17 P-2281, is this an article that you relied on in this
 18 case?
 19 A. Yes.
 20 Q. Is it instructive for your opinions and
 21 significant to them?
 22 A. Yes.
 23 Q. Is it an authoritative text?
 24 A. Yes.
 25 Q. Again, as you've done before, tell us what

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2 the title is and the authors first.
 3 A. The author is Dr. Mostafa. It appeared in
 4 European Urology in 2014. The title is:
 5 Single-incision mini-slugs versus standard
 6 midurethral slings in surgical management of female
 7 stress urinary incontinence: An updated systematic
 8 review and meta-analysis of effectiveness and
 9 complications.
 10 Q. And this meta-analysis, how many years did
 11 it cover in terms of the breadth of the literature?
 12 A. From 1996 to 2013.
 13 Q. And, briefly, what are the things about
 14 this article that inform your opinion?
 15 A. They discussed the fleece ends of the mesh
 16 and that it leads to a lower --
 17 MR. CAMPBELL: Excuse me, Your Honor.
 18 Again, it's being delivered in a way
 19 contrary to Your Honor's ruling.
 20 THE COURT: If you could just
 21 briefly -- well, repeat your question.
 22 BY MR. ANDERSON:
 23 Q. How does this inform your opinions?
 24 A. They describe a lower success rate for
 25 the --

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1 DIRECT - ROSENZWEIG
 2 MR. CAMPBELL: Judge, excuse me, he's
 3 repeating hearsay.
 4 MR. ANDERSON: Can I try again, Your
 5 Honor?
 6 THE COURT: Please.
 7 BY MR. ANDERSON:
 8 Q. Does this support the opinions you've
 9 offered here today?
 10 A. Yes.
 11 Q. What opinions does it support?
 12 A. The fact that the fleece ends of the TVT
 13 Secur do not hold, and, therefore, that defect leads
 14 to the harm, recurrent stress urinary incontinence,
 15 requiring another procedure.
 16 Q. Thank you. Showing you what we have marked
 17 as tab 23, Plaintiff's Exhibit 1185, is this an
 18 article that you reviewed and relied upon in this
 19 case?
 20 A. Yes.
 21 Q. Does it instruct your opinions and is it
 22 significant to them?
 23 A. Yes.
 24 Q. Is this an authoritative text?
 25 A. Yes.

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1 DIRECT - ROSENZWEIG
 2 Q. First of all, what is the title of the
 3 study?
 4 A. TVT Secur, in parentheses, hammock, versus
 5 TVT Obturator: A randomized trial of suburethral
 6 sling operative procedures.
 7 Q. And the author?
 8 A. Dr. Hota.
 9 Q. And is there anything about this article
 10 that supports your opinions? What opinions of yours
 11 does this article support?
 12 A. That the holding mechanism of the fleece
 13 ends of the TVT Secur was defective. It did not
 14 hold, and women had recurrent stress urinary
 15 incontinence. They found 50 percent of women after
 16 one year were still leaking urine.
 17 Q. Thank you. Going back to Plaintiff's
 18 P-1128, the article that we showed, the internal
 19 document that we showed the jury a few minutes ago;
 20 correct?
 21 A. Yes.
 22 Q. If we could just go to page 3 of this
 23 document at the top, with regard to Professor
 24 Nilsson's comments there about "no cutting edge,
 25 blade, is a very good thing," and then underneath

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2 that, under the handle prototype one, "inserters must
 3 be stiff and rounded," do you see that?
 4 A. Yes.
 5 Q. Is that something you reviewed and relied
 6 upon in this case?
 7 A. Yes.
 8 Q. Why is it significant, if at all, to your
 9 opinions regarding the nature of the defective design
 10 of the Secur?
 11 A. What this is discussing is the arrowhead
 12 inserter. It's too sharp. Defective because it is
 13 too sharp. It drags across the delicate vaginal
 14 tissue. It harms the delicate vaginal tissue, which
 15 could then lead to the tissue to break down and cause
 16 an erosion. Also leads to inflammation. It starts
 17 that process of chronic inflammation, chronic foreign
 18 body reaction, more scarring.
 19 Q. What is significant, if anything, to the
 20 fact that Dr. Nilsson said the inserter should not be
 21 a cutting blade?
 22 A. That it should not be sharp and drag
 23 against the tissue.
 24 Q. Turn with me, if you would, to tab -- if
 25 you can go back to that, inserter must be stiff and

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35

DIRECT - ROSENZWEIG

1 case?
 2 A. Yes.
 3 Q. Why?
 4 A. This is an e-mail string between Ethicon
 5 employees. It is from Price St. Hilaire, marketing
 6 director worldwide, and it's describing a survey of
 7 doctors. It's what's called a VOC, or voice of
 8 consumers, consumers being doctors, and they're
 9 giving feedback. What the document shows is
 10 67 percent of doctors felt that the inserter was too
 11 sharp, that the arrowhead inserter was too sharp.
 12 Q. Thank you. Does that further inform and
 13 support the opinions as you've addressed them to the
 14 jury here today?
 15 A. Yes.
 16 Q. This is tab 26, P-0842. Is this a document
 17 that you reviewed and relied upon?
 18 A. Yes.
 19 Q. Did you ask us to help create a slide with
 20 the images of the TVT Secur?
 21 A. Yes.
 22 Q. What are we seeing here in this image?
 23 A. This is an image of the TVT Secur device,
 24 and what is circled is the sharp arrowhead-like

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2 rounded, down further, if you could, under
 3 criticality of proper assessment, do you see where it
 4 says "learning curve for Nilsson was 100 patients
 5 before he was very good with very dry results," do
 6 you see?
 7 A. Yes.
 8 Q. You talked a little bit about learning
 9 curve a little while ago.
 10 A. Yes.
 11 Q. Can you explain whether or not this is
 12 significant to your opinions?
 13 A. Yes, it is.
 14 Q. Why?
 15 A. This is a very experienced surgeon, pelvic
 16 surgeon, key opinion leader, consultant for Ethicon,
 17 documenting that the learning curve is around 100
 18 patients to be able to do this procedure safely and
 19 effectively.
 20 Q. Thank you. If we could go to Plaintiff's
 21 tab 25, P-1063, tell us if you reviewed and relied
 22 upon this internal Ethicon document in forming your
 23 opinions in this case.
 24 A. Yes.
 25 Q. Was it significant to your opinions in this

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DIRECT - ROSENZWEIG

1 scalpel-like inserter.
 2 Q. Do you have an opinion as to whether that
 3 is safe or unsafe in women's tissue while inserting a
 4 medical device?
 5 A. It is unsafe.
 6 Q. Do you have an opinion as to whether or not
 7 that sharp arrowhead makes the TVT device, is one
 8 other aspect of its defective nature?
 9 A. Yes.
 10 Q. What is that opinion?
 11 A. That that is one of the characteristics of
 12 the TVT Secur device that makes it unsafe. The
 13 reason why it makes it unsafe is the harm to women is
 14 that it can cause pain and it can cause the tissue to
 15 break down, which leads to an erosion.
 16 Q. Going now to tab 27, Plaintiff's 1185, is
 17 this an article that you reviewed and relied upon in
 18 forming your opinions in this case?
 19 A. Yes.
 20 Q. Is it scientifically reliable and
 21 authoritative?
 22 A. Yes.
 23 Q. Okay. Tell us what the title is, what it
 24 was designed to do at the top.

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DIRECT - ROSENZWEIG

2 A. Do you want me to identify it?

3 Q. Yes. We've already identified it. This is

4 Hota, exactly.

5 A. They found two things in the study. One,

6 in one year, 50 percent of women were not cured.

7 They found a 19 percent erosion rate.

8 Q. And do you have an opinion as to whether or

9 not a 19 percent erosion rate of the TVT Secur device

10 would be safe or unsafe for women?

11 A. It is unsafe for women.

12 Q. Do you have an opinion as to whether or not

13 a 19 percent erosion rate would be an unreasonably

14 unsafe device?

15 A. It would be an unreasonably unsafe device.

16 Q. Thank you. And if we can turn back to

17 Plaintiff's Exhibit 2561, the Hota article, tab 18,

18 does this inform or instruct your opinions regarding

19 the scalpel-shaped tip?

20 A. Yes.

21 Q. Briefly, how so?

22 A. They had at one year --

23 Q. Doctor, does this support your opinions

24 regarding scalpel-shaped tip?

25 A. Yes.

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DIRECT - ROSENZWEIG

1 A. Correct.

2 Q. How is that significant to your opinions in

3 this case, if at all?

4 A. One of the defects of the device is that

5 the fleece tips didn't hold. If the fleece tips

6 don't hold, the mesh moves and migrates. If it moves

7 and migrates, it's not there to hold up the middle

8 portion of the urethra. The harm is that women will

9 then leak urine again and will need another surgery

10 to fix that leakage.

11 Q. Thank you. Going now to tab 30, can you

12 please identify this for the record?

13 A. This is an abstract --

14 Q. Let me ask you this.

15 A. Yes.

16 Q. Is it authoritative?

17 A. Yes.

18 THE COURT: P-0238?

19 MR. ANDERSON: Yes, ma'am.

20 THE WITNESS: This is another paper

21 from Krofta entitled: One year prospective

22 follow-up of the TVT Secur for treatment of

23 stress urinary incontinence.

24 BY MR. ANDERSON:

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DIRECT - ROSENZWEIG

1 Q. How does it support those opinions?

2 A. Because the harm that the scalpel-shaped

3 tip created, which was dragging through the tissue of

4 the vagina, irritating the tissue, leading to the

5 tape becoming eroded through the vaginal tissue.

6 Q. Thank you, Doctor. Have you reviewed

7 internal Ethicon documents related to the reported

8 patient outcomes of the Secur device?

9 A. Yes.

10 Q. Turn, please, to tab 29, Plaintiff's

11 Exhibit 1327. With regard to this Ethicon document,

12 please tell us how that is significant to your

13 opinions regarding reported patient outcomes of the

14 Secur device.

15 A. This is an internal Ethicon report from

16 May 29, 2012.

17 Q. Did the internal report include the Secur

18 device?

19 A. The Secur device was associated with an

20 inferior patient reported cure rates and had a higher

21 reoperation rate when compared to the full-length

22 slings.

23 Q. Is that what we are seeing on the screen

24 right now?

25

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DIRECT - ROSENZWEIG

1 Q. How does this impact or inform your

2 opinions in this case?

3 A. This shows that the fleece ends were

4 defectively designed. They did not hold. Therefore,

5 women had a higher rate of recurrence of stress

6 urinary incontinence and needed to have a second

7 surgical procedure, either a Burch procedure, like I

8 perform, or a retropubic sling, like was placed in

9 Ms. Engleman.

10 Q. Going to Plaintiff's Exhibit P-2356, it is

11 tab 31, is this something you reviewed and relied

12 upon in forming your opinions in this case?

13 A. Yes.

14 Q. Is this significant to your opinions?

15 A. Yes.

16 Q. Is this an authoritative text?

17 A. Yes.

18 Q. Can you please explain what was being done

19 here and who the authors were, and then we'll get

20 into how it informs your opinions?

21 A. This is from a Dr. Tommaselli. The title

22 is: Efficacy and safety of the TVT Secur in the

23 treatment of female stress urinary incontinence: A

24 systematic review.

25

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2 Q. And does this support the opinions
3 regarding the defective nature of the design of the
4 TVT Secur device that you've offered here today?
5 A. Yes.
6 Q. Briefly, how so?
7 A. That the fleece tips did not hold.
8 Patients had a higher rate of recurrence of their
9 stress incontinence. The sharp introducer dragged
10 across tissue, and there was a high 15 percent or,
11 excuse me, 16 percent erosion rate showing the defect
12 of both the fleece tip and the sharp tip introducer.
13 The harm that it caused was recurrence of stress
14 urinary incontinence and damage to the vagina leading
15 to erosion in the vagina.
16 Q. Thank you, Doctor. Does that inform your
17 opinions that the TVT Secur is defective?
18 A. Yes.
19 Q. Okay. Moving on to P-2362, Your Honor,
20 that's tab 32, did you review this in forming your
21 opinions in this case?
22 A. Yes.
23 Q. Is it significant to your opinions in this
24 case?
25 A. Yes.

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1 DIRECT - ROSENZWEIG
2 of the TVT Secur, the stiffness of the mesh of the
3 TVT Secur led to serious adverse events, and the
4 authors discouraged it from being used.
5 MR. CAMPBELL: Excuse me, Your Honor.
6 I move to strike. If we could be heard on
7 this?
8 (In-camera proceedings as
9 follows:)
10 (The court reporter reads back
11 the last question and answer.)
12 THE COURT: You were fine until we got
13 into the authors.
14 MR. CAMPBELL: Right. He keeps doing
15 that every single time.
16 MR. ANDERSON: Not every single time,
17 but if you would allow me to go up to him
18 and just to say do not say this is what it
19 said. So he was fine until he crossed
20 that. And, you know, we are working under
21 a different set of rules here than he's
22 used to, and we're trying. I will try to
23 back him off 20 feet from the line rather
24 than at the line, if I can, Your Honor.
25 THE COURT: What time is it exactly?

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2 Q. Is this an authoritative text?
3 A. Yes.
4 Q. Please describe for the jury the title and
5 the authors.
6 A. The author is Dr. Andrada Hamer. It was
7 published in the International Urogynecology journal
8 in 2013. The title is: One-year results of a
9 prospective randomized, evaluator-blinded,
10 multicenter study comparing TVT and TVT Secur.
11 Q. Okay. First of all, a lot of big words
12 there. Randomized, evaluator-blinded, multicenter
13 study, break that down for me, please.
14 A. Number one, they were looking forward, so
15 it was prospective. They randomly assigned someone
16 to the treatment, and the doctor that was doing the
17 treatment did not know which treatment the patient --
18 MR. CAMPBELL: Your Honor --
19 THE COURT: If you could just advise
20 the way in which -- well, what your opinion
21 is that this addressed.
22 BY MR. ANDERSON:
23 Q. What opinions does this address?
24 A. That the design defects of the TVT Secur,
25 the sharp edge of the TVT Secur, the fleece holders

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1 DIRECT - ROSENZWEIG
2 MR. ANDERSON: 2:00.
3 THE COURT: It's too early to take a
4 break. I will permit you to approach the
5 witness and speak to him privately, and
6 then it should not happen again.
7 MR. ANDERSON: Yes.
8 THE COURT: Pretty simple thing.
9 MR. ANDERSON: I agree. I agree. I
10 apologize, Your Honor.
11 THE COURT: Anything else while we're
12 back here?
13 MR. CAMPBELL: Yes, Your Honor, the
14 whole process, really it's, you know,
15 document after document and fleece tips and
16 sharp arrowheads. You know, if these all
17 go to those opinions, then I think, as
18 Mr. Snell keeps whispering to me, the
19 proper way to do that is: What is your
20 opinion? What's the basis for it? And the
21 articles can be stated. You know, I
22 understand the issues in a case of this
23 nature, but, you know, at this point it's
24 cumulative.
25 THE COURT: Response?

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2 MR. ANDERSON: Yes. He gave his
3 opinions at the beginning. Now we're going
4 through each one of the design defects.
5 And so one of those design defects, we've
6 tried to cover chronic foreign body
7 reaction. We've tried to cover all the
8 articles and documents. We're checking off
9 everything he said was defective. And this
10 is in regard to the fleece and the
11 arrowheads. If we can get into the article
12 more, it wouldn't be that. It would be
13 more in terms of failures and things like
14 that. So I will try and we've tried. We
15 have jumped a couple of documents to try to
16 not be repetitive because I felt it was
17 doing that.

18 THE COURT: That's enough. I
19 understand your objection. I'm not going
20 to curb the plaintiff.

21 MR. CAMPBELL: Okay. I'm just curious
22 about the schedule. I asked Mr. Anderson.
23 We've been very cooperative.
24 Just trying to, for the afternoon,
25 you're going to finish the general

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2 causation aspect of this?
3 MR. ANDERSON: I doubt it.
4 MR. CAMPBELL: I'm just asking.
5 MR. ANDERSON: The defects take a
6 while because then we have the nature of
7 the defects of the mesh and the tools and
8 then the procedure. So that takes a while.
9 Then we have to get into the IFU, and
10 there's three aspects of the IFU. So, you
11 know, I'll have a directed verdict motion
12 coming at me one of these days, and I want
13 to make sure I'm loaded for bear.

14 THE COURT: I do feel as if I'm
15 watching two parties in an extended dance
16 performance and they've been dancing the
17 steps together, and I understand that. I'm
18 anticipating also you are doing the best
19 you can, as you will, to see that this is
20 done as expeditiously as we can do it, but
21 you also can't cut corners. Let's go back
22 on the record.

23 (End of in camera proceedings.)
24 THE COURT: I believe that was P-2362;
25 is that correct?

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DIRECT - ROSENZWEIG

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2 MR. ANDERSON: That is correct, Your
3 Honor, and it was tab 32.

4 BY MR. ANDERSON:
5 Q. Okay. One more study, then we will move on
6 to some internal documents.
7 Looking at Plaintiff's P-2310, tab 33, is
8 this something you reviewed and relied upon in coming
9 to your opinions in this case?
10 A. Yes.
11 Q. Is it significant to your opinions in this
12 case?
13 A. Yes.
14 Q. Is this an authoritative text?
15 A. Yes.
16 Q. Briefly describe what this is and how it
17 informs your opinions, very briefly?
18 A. This is a systematic review, which
19 describes the results for mini slings, including the
20 TVT Secur.
21 Q. And, briefly, how does it inform your
22 opinions?
23 A. It showed that there was a low success
24 rate.
25 Q. Doctor, moving on from that, what is a

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DIRECT - ROSENZWEIG

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2 systematic review?
3 A. It is a review of literature that combines
4 all the studies together to draw a conclusion about a
5 specific topic.
6 Q. And if we could now move on to Plaintiff's
7 Exhibit 34, 0842 -- actually, no, tab 35.
8 THE COURT: What is the number,
9 please? Mr. Anderson, I don't want to
10 interrupt, but the last number, P-2130, I
11 was unable to locate that.
12 MR. ANDERSON: P-2310.
13 THE COURT: P-2310, thank you.
14 MR. ANDERSON: But now we are on tab
15 35, please.
16 THE COURT: That number is?
17 MR. ANDERSON: P-1677.
18 THE COURT: Thank you.
19 MR. ANDERSON: Thank you, Your Honor.

20 BY MR. ANDERSON:
21 Q. Is this something that you have reviewed
22 and relied upon in coming to your opinions in this
23 case?
24 A. Yes.
25 Q. Is it significant to your opinions?

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2 A. Yes.
3 Q. First of all, what is it?
4 A. This is an internal Ethicon document. It
5 is a PowerPoint presentation.
6 Q. And what is significant to you, if at all,
7 about this communication?
8 A. If we go to page 39.
9 Q. Page 39 of the PowerPoint?
10 A. Yes, entitled "watch out."
11 Q. Okay. Please explain why this is important
12 to your opinions in this case.
13 A. It describes a risky situation when
14 launching a device without having data.
15 Q. Under "after our risky situation with Secur
16 and increased demand for at least one-year data," is
17 that what you're referring to?
18 A. Yes.
19 Q. How does that inform your opinions in this
20 case?
21 A. That there was insufficient data prior to
22 the launch of the product.
23 Q. Turning your attention to tab 36, P-0241,
24 is this something that you've reviewed and relied
25 upon in this case?

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2 A. Yes.
3 Q. And is it something significant to your
4 opinions?
5 A. Yes.
6 Q. Why is this significant to your opinions?
7 A. This is an e-mail from Dr. Aaron Kirkemo,
8 who is a urologist, pelvic surgeon, and medical
9 director at Ethicon, to other medical directors, and
10 this e-mail is describing what damage will be done to
11 the brand if a product is released without data just
12 like the TVT Secur.
13 Q. Does that inform your opinions in this
14 case?
15 A. Yes.
16 Q. What opinion does it inform?
17 A. That there was not enough data on this
18 product to launch the product market.
19 Q. Tab 38, Plaintiff's P-0286, is this a
20 document that you reviewed and relied upon in forming
21 your opinions in this case?
22 A. Yes.
23 Q. Is it significant to your opinions?
24 A. Yes.
25 Q. Explain to the jury what this is.

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1 DIRECT - ROSENZWEIG 51
2 A. This is an e-mail string --
3 MR. ANDERSON: Oh, take it down,
4 please.
5 BY MR. ANDERSON:
6 Q. Why is this important to your opinions?
7 A. This is an internal Ethicon e-mail from the
8 medical director of Ethicon Australia, Dr. Aran
9 Maree.
10 Q. How does this inform your opinions in this
11 case, if at all?
12 A. It's describing the experience with doctors
13 in Australia using the TVT Secur device.
14 Q. And what about their experience in
15 Australia using the Secur device?
16 A. They were very concerned that there was a
17 high failure rate of the device, specifically at six
18 weeks.
19 Q. If we could turn to P-1460, tab 37, is this
20 significant to your opinions in this case?
21 A. Yes.
22 Q. And is this something that you relied on in
23 forming your opinions in this case?
24 A. Yes.
25 MR. ANDERSON: Publish it, please.

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1 DIRECT - ROSENZWEIG 52
2 BY MR. ANDERSON:
3 Q. Who is this e-mail to and from?
4 A. This is an e-mail from Dan Smith, engineer
5 and co-patent holder of the Secur to other key
6 Ethicon employees.
7 Q. And if we turn to page 2, bullet point 2,
8 please, is this informative to your opinions?
9 A. Yes.
10 Q. Why?
11 A. Dan Smith is writing that the TVT Secur
12 device is a failure and they should not continue the
13 product line.
14 Q. Thank you. Showing you what's been marked
15 as P-1962, is this a document that you've seen and
16 relied upon in forming your opinions in this case?
17 A. Yes.
18 Q. And is it significant to your opinions?
19 A. Yes.
20 Q. And what is this document and why is it
21 significant to your opinions?
22 A. This is the Johnson & Johnson credo, and
23 what the credo states is that the first
24 responsibility is to doctors, nurses, and patients.
25 Q. Anything else about this document that is

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DIRECT - ROSENZWEIG

2 significant to your opinions?

3 A. They also state that they pay for their

4 mistakes.

5 Q. Is that significant to your opinions in

6 this case?

7 A. Yes.

8 Q. Do you agree with that?

9 A. Yes.

10 Q. Next document, tab 41, Your Honor, is

11 P-2321.

12 Is this a study that you reviewed in

13 forming your opinions in this case?

14 A. Yes.

15 Q. Was it significant to your opinions?

16 A. Yes.

17 Q. Is this authoritative text?

18 A. Yes.

19 Q. Briefly tell us what this was.

20 A. This is a study by Dr. Haab, who is a

21 scientist, a pelvic surgeon.

22 Q. Tell us how this instructs your opinions.

23 A. This is a four-and-a-half year study that

24 found that only 31 percent of women were dry.

25 MR. CAMPBELL: I object for the same

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DIRECT - ROSENZWEIG

1 Does the event of mesh contraction and

2 shrinkage occur before or after the implantation of

3 mesh in a woman's body?

4 A. After it's implanted.

5 Q. Have you seen documents or read depositions

6 of employees at Ethicon regarding when the company

7 became aware of mesh contraction and mesh shrinkage?

8 A. Yes.

9 Q. Have you reviewed articles by their

10 consultants regarding when mesh contraction and

11 shrinkage first occurred?

12 A. Yes.

13 Q. Tab 42, P-2243, have you reviewed and

14 relied upon this?

15 A. Yes.

16 Q. Is it authoritative?

17 A. Yes.

18 Q. What opinions of yours does this support?

19 A. That mesh contracts.

20 Q. Okay. And what year is this study?

21 A. 1998.

22 Q. And who are the authors of the study?

23 A. Dr. Klinge, Dr. Klosterhalfen.

24 Q. In terms of in relation to Ethicon, do you

25

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2 reasons and I move to strike.

3 THE COURT: If you'll re-ask your

4 question, please.

5 MR. ANDERSON: Okay, Your Honor.

6 BY MR. ANDERSON:

7 Q. Does this support your opinions in this

8 case?

9 A. Yes.

10 Q. What opinions in this case that you have

11 does this support?

12 A. That the TVT Secur has a very low success

13 rate.

14 Q. How would you describe very low success

15 rate?

16 A. Less than 50 percent.

17 Q. Have you reviewed Plaintiff's P-2243, which

18 is tab 42?

19 A. Yes.

20 Q. Is this an article that you've reviewed in

21 this case?

22 A. Yes.

23 Q. Before we get into that, let me ask you

24 this: We've talked a little bit about contraction

25 and shrinkage.

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1 know who these consultants were?

2 A. These were doctors working in Germany and

3 also they were Ethicon consultants.

4 Q. And, again, the year of this is?

5 A. 1998.

6 Q. Thank you. Please tell us what it is about

7 shrinking -- strike that.

8 Do you have an opinion as to whether or not

9 the TVT Secur mesh shrinks?

10 A. Yes.

11 Q. Do you have opinions whether it shrinks in

12 the woman's tissue after it's implanted?

13 A. Yes.

14 Q. Do you have an opinion as to how much the

15 mesh shrinks once it's implanted?

16 A. Yes.

17 Q. How much is that?

18 A. Approximately 30 to 50 percent.

19 Q. What is your basis for that opinion?

20 A. The scientific knowledge, from the

21 literature, and internal Ethicon documents.

22 Q. Tab 43, P-1846, have you reviewed tab 43,

23 P-1846?

24 A. Yes.

25

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2 Q. Okay. And is it significant to your
3 opinions?
4 A. Yes.
5 Q. Okay. And did you rely on it in forming
6 your opinions?
7 A. Yes.
8 Q. What is 1846?
9 A. It is an e-mail from Dr. Holste, who is a
10 scientist at Ethicon, to another scientist at
11 Ethicon, Dr. Engel, including Dr. Boris Batke, who is
12 a scientist, and it's discussing mesh shrinkage.
13 Q. With regard to these first statements back
14 in, I guess, this is March 13, 2006: This was our
15 scientific statement on mesh shrinkage: Basically
16 small pores, heavyweight meshes induce more fibrotic,
17 bridging tissue reaction causing more mesh shrinkage
18 during maturing of the collagenous tissue. See my
19 presentation about biocompatibility.
20 Is that attached to this e-mail?
21 A. Yes.
22 Q. Does this inform your opinions regarding
23 the defective nature of the heavyweight, small-pore
24 mesh in the Secur device?
25 A. Yes.

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1
2 A. Yes.
3 Q. What is that opinion?
4 A. That it is a defect of the mesh in the
5 Secur device.
6 Q. And who wrote that internal report at
7 Ethicon?
8 A. That is a scientist, Dr. Holste.
9 Q. Showing you what's been marked as P-0791,
10 that's tab 44, Your Honor, have you reviewed and
11 relied upon this document?
12 A. Yes.
13 Q. Did it inform your opinions in this case?
14 A. Yes.
15 Q. Is this an authoritative text?
16 A. Yes.
17 Q. Who was this written by?
18 A. Dr. Klosterhalfen.
19 Q. Who is Dr. Klosterhalfen?
20 A. He is a scientist in Germany and consultant
21 for Ethicon.
22 Q. What year is this publication?
23 A. 2005.
24 Q. And what opinions of yours does this
25 article support or not support?

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2 Q. How so, Doctor?
3 A. That the characteristics of the mesh lead
4 to chronic foreign body reaction, scar plating, and
5 mesh contraction.
6 Q. With regard to the internal report that's
7 attached to this e-mail, do you have that in front of
8 you?
9 A. Yes.
10 Q. Is that significant to your opinions?
11 A. Yes.
12 Q. How so?
13 A. Further describes that the chronic foreign
14 body reaction, chronic inflammatory reaction, scar
15 plating leads to mesh shrinkage.
16 Q. What year was this internal report done at
17 Ethicon?
18 A. 2006.
19 Q. Do you have an opinion as to whether or not
20 a heavyweight, small-pore mesh that causes this mesh
21 shrinkage during maturing of collagenous tissue, is
22 that applicable to the Secur mesh?
23 A. Yes.
24 Q. Do you have an opinion as to whether that's
25 another defect of the Secur mesh?

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2 A. That there is more fibrosis, scarring, and
3 contraction with heavy, stiff, small-pore mesh.
4 Q. Okay. Do you have an opinion as to whether
5 or not there were meshes available to Ethicon that
6 were not heavy, stiff, small-pore mesh as of
7 September 2006 when this product was launched?
8 A. Yes.
9 Q. And what are those?
10 A. There are larger-pore, lighter-weight
11 meshes that were available.
12 Q. And those lighter-weight, larger-pore
13 meshes that were available, were any of those
14 manufactured by Ethicon as of September 2006?
15 A. Yes.
16 Q. And what was the name of the lightweight
17 large-pore mesh that was available to Ethicon in 2006
18 that would have been lighter-weight, larger-pore,
19 less stiff and rigid than the heavyweight, small-pore
20 Prolene in the Secur?
21 A. Yes. There were two. There was one called
22 Vypro, which was created in the late '90s, and
23 another called Ultrapro, which was created in the
24 early 2000s and was available in 2003.
25 Q. Do you have an opinion as to whether those

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- 2 were reasonable, economical, and feasible devices
3 instead of the heavyweight Prolene in the Secur
4 device?
5 A. Yes.
6 Q. What is that opinion?
7 A. That it was reasonable to place that in
8 women's pelvises instead of the Prolene mesh. It
9 would have been safer to place that.
10 Q. Showing you now what we will mark as
11 Plaintiff's Exhibit 0933, which is tab 45, Your
12 Honor, you reviewed and relied upon this in forming
13 your opinions in this case?
14 A. Yes.
15 Q. Is it significant to your opinions?
16 A. Yes.
17 Q. Please explain what this is for the jury.
18 A. This is an e-mail between medical
19 directors, Axel Arnaud, medical director,
20 Dr. Weisberg, medical director, discussing mesh
21 shrinkage.
22 Q. What year is this e-mail sent discussing
23 mesh shrinkage?
24 A. It was November 26, 2002.
25 Q. If we can go down to the paragraph that has

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- 1
2 Q. Do you have an opinion as to whether or not
3 that the Secur device, with the heavyweight,
4 small-pore, with 30 percent shrinkage, is a defect in
5 that mesh?
6 A. Yes.
7 Q. What is it?
8 A. That is a defect.
9 Q. Going now to tab 44, P-1235, is this
10 something that you have reviewed and relied upon in
11 forming your opinions in this case?
12 A. Yes.
13 Q. Is it significant to your opinions?
14 A. Yes.
15 Q. And can you please identify this document
16 for the jury?
17 A. This is an internal Ethicon document from
18 December of 2006 from a Dr. Kerstin Spychag, and it
19 is: State of the knowledge in mesh shrinkage - what
20 do we know?
21 Q. What is it that Ethicon stated that mesh
22 shrinkage could lead to in patients?
23 A. Discomfort, chronic pain, and recurrence.
24 Q. If we look down to the first paragraph
25 under factors related to mesh shrinkage, if you could

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- 2 been highlighted, is this instructive to your
3 opinions at all, Dr. Rosenzweig?
4 A. Yes.
5 Q. How so?
6 A. This is discussing, first of all, that
7 there's a 30 percent shrinkage rate for mesh, and
8 there are various parameters that increase the risk
9 of shrinkage.
10 Q. What parameters are those that increase the
11 risk of shrinkage?
12 A. The material, the weave, the width.
13 Q. What is it about, if anything, the
14 material, weave, and width of the Prolene mesh in the
15 TVT Secur that would lead to 30 percent shrinkage?
16 A. The chronic foreign body reaction.
17 Q. Do you have an opinion as to whether that
18 is a defect in the -- another defect in the TVT Secur
19 device?
20 A. Correct.
21 Q. Do you have an opinion as to whether or not
22 30 percent shrinkage of a heavyweight, small-pore
23 mesh, that has more chronic foreign body reaction in
24 a woman's vagina tissue, is a safe or unsafe device?
25 A. It is unsafe.

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- 1
2 look at that, please.
3 A. Yes.
4 Q. Is this significant to your opinions?
5 A. Yes.
6 Q. Before I go there, let me just ask you
7 this. We saw the word hernia in there; right?
8 A. Yes.
9 Q. Have you reviewed documents, internal
10 documents, scientific literature, as well as
11 depositions of Ethicon employees with regard to the
12 Prolene mesh that's used in TVT Secur and its history
13 of use at Ethicon?
14 A. Yes.
15 Q. When was the Prolene mesh first put on the
16 market by Ethicon? What you've described as this
17 heavyweight, small-pore, rigid mesh, when was that
18 first put on the market?
19 A. In the '70s.
20 Q. What application was that used for from the
21 '70s forward?
22 A. Treatment of hernias.
23 Q. And then did there come a point in time
24 where Ethicon developed a new mesh to replace this
25 hernia mesh from the '70s?

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2 A. Yes.
 3 Q. At what point in time was that?
 4 A. Late '90s.
 5 Q. What mesh was that that they developed
 6 after that?
 7 A. It was a lighter-weight, bigger-pore mesh
 8 called Vypro.
 9 Q. You mentioned Vypro a few minutes ago. You
 10 said also there was an Ultrapro lightweight mesh.
 11 When was that developed?
 12 A. In the early 2000s. It became available in
 13 approximately 2003.
 14 Q. So this article from December of 2006
 15 talking about shrinking meshes and about the factors
 16 related to mesh shrinkage, when did Ethicon first
 17 know that these factors were related to heavyweight,
 18 small-pore Prolene mesh used in the TVT Secur?
 19 A. In the '90s.
 20 Q. Does this inform your opinions in this
 21 case?
 22 A. Yes.
 23 Q. How so?
 24 A. Well, it describes the factors that are
 25 associated with mesh shrinkage.

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2 Q. Okay. And what are those?
 3 A. The weight of the mesh, the density of the
 4 mesh, the thickness of the individual fibers of the
 5 mesh, the surface area of the mesh, the pore size of
 6 the mesh, and the mesh architecture, such as how the
 7 mesh is cut.
 8 Q. I'm sorry.
 9 A. Go ahead.
 10 Q. Do you have an opinion as to whether or not
 11 the weight, surface area, pore size, and fiber
 12 architecture of the Prolene mesh in the TVT Secur
 13 device was safe or unsafe for patients?
 14 A. I have an opinion, yes.
 15 Q. What is it?
 16 A. That it's unsafe.
 17 Q. Why?
 18 A. Because of the contraction, chronic foreign
 19 body reaction, chronic inflammation associated with
 20 the stiff, heavy, small-pore, heavyweight mesh.
 21 Q. Thank you. Going now to tab 47.
 22 THE COURT: P-0863?
 23 MR. ANDERSON: We're going to move on
 24 from that one.
 25 THE COURT: All right. Thank you.

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2 MR. ANDERSON: We've covered that.
 3 BY MR. ANDERSON:
 4 Q. Before we move on, we were just talking
 5 about stiff rigid mesh. In your review of all the
 6 documents and literature in this case and the
 7 internal Ethicon studies and the depositions in this
 8 case, were you able to determine whether or not
 9 Ethicon ever did a long-term trial on the Secur mesh
 10 to examine contraction of the stiff mesh like was
 11 recommended in the 2002 internal communication that
 12 we looked at?
 13 A. No, they did not.
 14 Q. I'll go through a series of opinions with
 15 you now that we've covered this section of
 16 contraction.
 17 Do you have an opinion, Doctor, whether or
 18 not shrinkage and contraction of the Secur mesh can
 19 lead to chronic vaginal pain that cannot be cured or
 20 effectively treated?
 21 A. Yes.
 22 Q. And what is that opinion?
 23 A. That contraction of the mesh can lead to
 24 pain, pain with intercourse, that cannot be
 25 successfully treated.

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2 Q. Do you have an opinion, Dr. Rosenzweig,
 3 whether or not shrinkage and contraction of the Secur
 4 mesh can lead to chronic dyspareunia or lifelong
 5 painful sexual relations? Do you have an opinion?
 6 A. Yes.
 7 Q. What is that opinion?
 8 A. That mesh contraction can lead to lifelong
 9 pain with sexual intercourse.
 10 Q. Do you have an opinion, Doctor, based on
 11 all that you've reviewed in this case, whether or not
 12 shrinkage and contraction of the Secur mesh can lead
 13 to lifelong risk of recurrent erosions in the vaginal
 14 tissue?
 15 A. Yes.
 16 Q. And what is that opinion?
 17 A. That shrinkage and contraction of the heavy
 18 rigid stiff mesh can lead to lifelong risks of
 19 erosion.
 20 Q. Do you have an opinion, Dr. Rosenzweig,
 21 whether or not shrinkage or contraction of the Secur
 22 mesh leads to chronic urinary problems for patients?
 23 A. Yes.
 24 Q. And please explain that opinion.
 25 A. When the mesh contracts, it can irritate

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2 the urethra, and that can lead to urinary symptoms of
 3 pain with urination and contract and obstruct the
 4 urethra and make it difficult for a woman to empty
 5 their bladder. Or it can contract, in the case of
 6 the Secur, migrate away from the portion where it's
 7 supposed to be, and not treat the stress urinary
 8 incontinence and they start leaking again.

9 Q. Have you seen contracted Prolene mesh, like
 10 that used in the Secur mesh, associated with patient
 11 complications in your practice?

12 A. Yes, I have.

13 Q. Have you seen them documented in Ethicon
 14 reports, documents, and testimony?

15 A. Yes.

16 Q. Have you reviewed any literature or studies
 17 regarding a relationship between increased fibrotic
 18 reaction and patient complications like we talked
 19 about a few moments ago?

20 A. Yes.

21 Q. Turn to tab 48, if you would, please. This
 22 is Plaintiff's P-1712.

23 Is this something that you reviewed and
 24 relied upon in coming to your opinions in this case?

25 A. Yes.

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1 this regard?

2 A. Yes.

3 Q. Okay. Doctor, I'm going to go through, now
 4 that we've spent a good part of today talking about
 5 your opinions about the defective nature of the Secur
 6 mesh, I want to just ask you the following: Do you
 7 have an opinion as to whether or not the Secur mesh
 8 causes chronic foreign body inflammation?

9 A. Yes.

10 Q. Do you have an opinion as to whether or not
 11 the Secur mesh causes chronic inflammation?

12 A. Yes.

13 Q. Do you have an opinion as to whether or not
 14 the Secur mesh causes excessive scarring?

15 MR. CAMPBELL: Excuse me, Your Honor.
 16 I object. It's cumulative at this point.

17 THE COURT: Overruled.

18 BY MR. ANDERSON:

19 Q. Do you have an opinion as to whether or not
 20 the Secur mesh causes fibrotic bridging, scar plate
 21 encapsulation, and mesh shrinkage and contraction?

22 A. Yes.

23 Q. Do you have an opinion as to whether or not
 24 Ethicon failed to adequately study the TVT Secur
 25

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2 Q. Is this significant to your opinions in
 3 this case?

4 A. Yes.

5 Q. Is it an authoritative text?

6 A. Yes.

7 Q. Okay. Please just give us the title and
 8 the first author and then at least who these authors
 9 are. Then we'll talk about if you have any opinions
 10 that this supports.

11 A. Yes. The title is: Host response to
 12 synthetic mesh in women with mesh complications.

13 The lead author is Dr. Nolfi. One of the
 14 other contributing authors is Dr. Moalli, and it was
 15 published in 2016.

16 Q. Okay. And does this article support any of
 17 your opinions here today?

18 A. Yes.

19 Q. What opinions that you have here today does
 20 this article support?

21 A. That stiff mesh leads to deleterious
 22 consequences for women. It can lead to erosions of
 23 the mesh into the vagina or mesh contraction and
 24 pain.

25 Q. And this article supports those opinions in

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1 mesh?

2 A. Yes.

3 Q. Do you have an opinion as to whether or not
 4 the TVT Secur mesh is a defective implant procedure,
 5 defective technique, and defective absorbable fleece
 6 tips?

7 A. Yes.

8 Q. Do you have an opinion as to whether or not
 9 the implanter mechanisms or instruments are
 10 defective?

11 A. Yes.

12 Q. And do you have an opinion as to whether or
 13 not TVT Secur should have even been marketed in the
 14 first place?

15 A. Yes.

16 Q. And what is your opinion in this regard?

17 A. That TVT Secur should not have been
 18 marketed in the first place, that the introducer is
 19 defective, that the arrow tip, sharp arrow tip
 20 inserter is defective, that the fleece tip holding
 21 mechanism is defective, and that the mesh itself,
 22 being stiff and rigid, is defective.

23 Q. Do you have an opinion as to whether or not
 24 these design defects caused injury -- caused patient
 25

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2 complications?
3 A. Yes.
4 Q. What patient complications did these
5 defects in the Secur device cause for patient
6 complications?
7 A. Chronic pain, chronic pain with
8 intercourse, recurrent and multiple erosions of the
9 mesh through the vagina or onto other organs, urinary
10 symptoms, recurrence of stress urinary incontinence,
11 and voiding symptoms.
12 Q. Are these complications that you have
13 personally observed when cutting out heavyweight
14 mesh, including the Secur mesh, from women's vaginal
15 tissues?
16 A. Yes.
17 Q. And are these complications that you have
18 found when reviewing the literature, internal Ethicon
19 documents, and Ethicon employees' sworn testimony?
20 A. Yes.
21 Q. With regard to this last patient injury, do
22 you have an opinion as to whether or not the Secur
23 mesh increases the risk to women for the need for
24 multiple repeat surgeries to correct their
25 complications?

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2 A. Yes.
3 Q. Okay. Which of these complications can
4 require future surgery for Ms. Engleman and other
5 women?
6 A. All the complications I've described,
7 erosion, pain, pain with intercourse, recurrence of
8 stress urinary incontinence, and other urinary
9 symptoms.
10 Q. Doctor, you explained to the jury that week
11 in and week out in your practice that you treat women
12 from complications with mesh slings.
13 I want to ask you, with regard to these
14 additional surgeries, what is involved in an
15 additional surgery to remove the mesh like the Secur
16 mesh that you have in your patients?
17 A. Well, those surgeries are often quite
18 difficult because of scarring that has taken place,
19 that these are women that have had not only a
20 procedure, but sometimes a secondary procedure. So
21 they can be quite difficult and risky. There's risk
22 of injury to adjacent structures like the bladder and
23 urethra. So they are very difficult procedures.
24 Q. Are you aware from literature as well as
25 your own personal experience that, when a doctor

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2 intends to remove the mesh, the entirety of the mesh
3 cannot be removed physically?
4 A. Yes. I've seen that in the literature,
5 plus that is my personal experience.
6 Q. Is it sometimes physically impossible to
7 remove all the mesh even if you wanted to?
8 MR. CAMPBELL: Excuse me, Your Honor.
9 It's leading.
10 THE COURT: Rephrase your question.
11 BY MR. ANDERSON:
12 Q. Do you have an opinion, based upon your
13 experience, as to whether or not it can be physically
14 impossible to remove all the mesh?
15 A. Yes, it is often impossible to remove all
16 the mesh.
17 Q. Okay. Shifting gears a little bit, Doctor,
18 have you arrived at some expert conclusions and
19 formed opinions as to whether there were alternatives
20 for treating stress urinary incontinence that would
21 have been safer than the Secur mesh in 2006?
22 A. Yes.
23 Q. Let's go through those and talk about each
24 one.
25 Have you asked me to prepare a slide in

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2 this regard regarding what you believe the safer
3 alternatives are?
4 A. Yes.
5 THE COURT: Mr. Anderson, while you're
6 doing that, I'm just going to suggest our
7 jury stand up a little bit, stretch a
8 little bit.
9 Members of the jury, you may be
10 wondering why we're continuing without a
11 break. It's because we want to let you go
12 at 3:30 today. We thought we would just go
13 straight through until 3:30 and let you go
14 a little bit earlier. I didn't want you to
15 think we forgot what we promised, which is
16 a break in the afternoon. We thought, it's
17 right before a holiday, let's see if we can
18 get you out of here a little earlier.
19 That's what we're doing. It doesn't hurt
20 to stretch. This is a long day in a warm
21 room. Thank you.
22 BY MR. ANDERSON:
23 Q. Okay. Doctor, we were talking about safer
24 alternatives to treat stress urinary incontinence
25 than the Secur mesh; right?

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2 A. Yes.

3 Q. Okay. Could you please just list for the

4 jury what you believe the safer alternative products

5 would have been?

6 MR. CAMPBELL: Excuse me, Your Honor.

7 THE COURT: Yes?

8 MR. ANDERSON: It wouldn't print.

9 This printer's down. He didn't know he

10 wasn't supposed to publish that.

11 THE COURT: Thank you for explaining.

12 BY MR. ANDERSON:

13 Q. What are the safer alternatives that you

14 would propose?

15 A. Well, one of the safer alternative designs

16 is using suture. As I described before, sutures are

17 used when doing a Burch procedure or the pubovaginal

18 sling procedure. The other alternative design is to

19 use a lightweight, large-pore, less-stiff mesh.

20 MR. ANDERSON: If I may approach, Your

21 Honor, to hand this?

22 MR. CAMPBELL: What is that?

23 MR. ANDERSON: It's a suture.

24 BY MR. ANDERSON:

25 Q. So, Doctor, let's go to your first safer

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2 A. About 30 to 40 feet.

3 Q. Okay. Now, who are those sutures made by?

4 A. Ethicon.

5 Q. Were Ethicon sutures available in September

6 of 2006?

7 A. Yes.

8 Q. 1996?

9 A. Yes.

10 Q. Even before?

11 A. Yes.

12 Q. Okay. What sutures do you use in your

13 Burch patients?

14 A. I mostly use a delayed absorbable suture.

15 There has been studies that have shown there's no

16 difference between the success rate when you use

17 delayed absorbable suture versus a permanent suture.

18 Q. Move your microphone over a little bit.

19 She's straining. Thank you.

20 In terms of efficacy, do you have the same

21 efficacy as Secur with the -- let me back up.

22 What kind of efficacy do you have with, in

23 other words, effectiveness do you have with your

24 Burch patients?

25 A. The same or better than the Secur.

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2 alternative with regard to a suture repair.

3 What is this?

4 A. This is what a suture, the package that it

5 comes in. They open it up in the operating room by

6 the scrub nurse and takes it out of the package.

7 It's a pretty small suture. So this is what a piece

8 of suture looks like with a little needle on the end

9 in order to sew into tissue.

10 Q. How much of that would be left in the body

11 after it is sewn and tied?

12 A. Well, you would probably leave, depending

13 on how thick the tissue is that you're sewing, so if

14 this is the end right here, maybe an inch, maybe a

15 little bit longer. Once you sew it into place, you

16 tie a knot, and you don't want to leave very much on

17 the ends of the knot. So less than an inch.

18 Q. How much of those less-than-an-inch sutures

19 would you use in your Burch procedures?

20 A. Four.

21 Q. And so how much total suture material would

22 that be for the Burch?

23 A. 4 to 6 inches.

24 Q. How much suture material is woven into the

25 TVT Secur mesh?

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2 Q. Okay. Do you have an opinion as to whether

3 either the use of a suture in the Burch or the

4 pubovaginal sling would be a safer alternative for

5 stress urinary incontinence than the Secur product?

6 MR. CAMPBELL: Judge, I object. I

7 believe it was the subject of a motion, but

8 I'm not sure.

9 THE COURT: Brief sidebar, please.

10 (In-camera proceedings as

11 follows:)

12 (The court reporter reads back

13 the last question.)

14 MR. CAMPBELL: The alternative that's

15 required is a safer alternative design.

16 Burch procedures and sling procedures are

17 surgical procedures, and it's not a

18 product.

19 I would defer to others, but I thought

20 that was a motion that was filed in that

21 regard. But I defer if it's not. But in

22 any case, the issue is safer alternative

23 design, not some other surgical procedure

24 as opposed to the device.

25 MR. ANDERSON: That was the

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defendant's argument both in the last case, and it was excluded there as well, and it should be here. New Jersey Products Liability Act says that you can -- it has to be a product that is a safer alternative design.

This product, as is sitting up there on the stand, is the Prolene product. The only difference between the Prolene product up there is suture material, and the Prolene product that's in the TVT Secur has 40 feet of it and is woven into a mesh and has all these inserter tools and all these other things.

We're saying this product is just as fine when used with a surgical device to pull the tissue up underneath the urethra. One is a large piece of mesh; one is a small piece of mesh.

THE COURT: What is the product that the witness has on the stand?

MR. ANDERSON: Those are just Prolene sutures like surgeons have in every operating room in the world.

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MR. CAMPBELL: If I may respond to that, I would then say, if that's the presentation of it, to my knowledge, there's no disclosure that sutures are the safer alternative design to the Secur. That's just not been the statement. I've heard Dr. Rosenzweig say that he uses the pubovaginal sling and the Burch procedure, but I've never heard him say, either at deposition in this case or in his reports, that the suture is the safer alternative design.

THE COURT: He has just testified that it is the suture that he uses when he does the Burch; is that correct?

MR. ANDERSON: No. He said that is available to be used by doctors when they use the Burch. Some use absorbable; some use polypropylene synthetic non-absorbables. There's an array of sutures that are available. So this is just one suture that's available to do that procedure. Different doctors use different things.

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THE COURT: The question that you asked this doctor, before he began testifying as to the sutures, was what were the surgical alternatives available in 2006; correct?

MR. ANDERSON: That's correct.

THE COURT: And that's the question that he is answering. Insofar as you intend to use this testimony to support the design defect, it won't work. I agree with counsel, with defense in this matter. This is not testimony that goes to design defect.

MR. ANDERSON: Respectfully, Your Honor, we would like an opportunity to brief that because that was exactly what was decided in the Carlino case and the post-trial motions and support for it.

THE COURT: I'll look for your briefs on Monday from both of you.

MR. CAMPBELL: Thanks for the time.

(End of in camera proceedings.)

THE COURT: Continue.

MR. ANDERSON: Thank you, Your Honor.

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BY MR. ANDERSON:

Q. Do you have an opinion, Doctor, as to whether or not the Burch or the pubovaginal sling procedures would have been safer procedures than the Secur procedure as of September 2006?

MR. CAMPBELL: Same objection, Your Honor.

THE COURT: So noted.

THE WITNESS: Yes, they would be safer alternative procedures.

BY MR. ANDERSON:

Q. We talked a little bit about Ethicon meshes that were available in September 2006 and before that you believed would be softer and lighter.

Do you recall that part of your testimony?

A. Yes.

Q. In your review of the internal Ethicon documents, did you come across any documents where they did a side-by-side comparison between this stiff rigid mesh used in the Secur and the lighter-weight meshes that Ethicon began selling in the late '90s?

A. Yes.

Q. Handing you what we will mark as Plaintiff's Exhibit 49, is this a document that you

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2 have reviewed and relied upon in this case?

3 A. Yes.

4 Q. Is it informative to your opinions in this

5 case?

6 A. Yes.

7 Q. What about this is informative to your

8 opinions in this case?

9 A. This is a PowerPoint presentation from an

10 Ethicon scientist. His name is Boris Batke. And it

11 is demonstrating the difference between heavyweight,

12 small-pore mesh and lightweight, large-pore mesh.

13 Q. And if we could turn to the side-by-side,

14 did you find a slide that had a side-by-side

15 comparison?

16 A. Yes.

17 MR. CAMPBELL: Excuse me, Your Honor.

18 Again, I believe this is a disclosure

19 issue.

20 THE COURT: I'm sorry?

21 MR. CAMPBELL: I believe this is a

22 disclosure issue.

23 THE COURT: Let's have a brief sidebar

24 on this.

25 (In-camera proceedings as

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2 follows:)

3 THE COURT: How is this a disclosure

4 issue?

5 MR. CAMPBELL: Your Honor,

6 Dr. Rosenzweig has most definitely

7 identified Ultrapro as a safer alternative

8 design. No question. And when the

9 testimony came up about Vypro earlier,

10 Mr. Snell said, you know, that wasn't part

11 of his disclosure as an alternative design.

12 I had seen the documents on Vypro, but I

13 believe Mr. Rosenblatt has checked and it's

14 not in his report.

15 MR. ROSENBLATT: Dr. Rosenzweig did

16 testify that he's not offering Vypro as a

17 safer alternative, and his basis was that

18 because it was a multifilament mesh.

19 MR. SNELL: That's consistent with the

20 testimony he's given to me, Your Honor,

21 because I had deposed that witness on

22 multiple occasions. He has never

23 identified Vypro as a safer, feasible,

24 alternative design.

25 THE COURT: What testimony has he

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1 provided on Vypro in this case, if any?

2 MR. ANDERSON: This is more

3 historical. I did not ask him if Vypro was

4 a safer alternative. We're jumping the

5 gun. This is historically when they first

6 developed and knew there was a need for

7 lightweight, large-pore meshes. This just

8 happened to be the first one, and it was

9 put out in 1998, which was the same year

10 they started to do the TVT. That's the

11 irony in the case and that's what we're

12 trying to prove. Over here they were doing

13 lighter-weight, large-pore mesh. This just

14 happens to be the first generation of them.

15 And as we develop the testimony, we'll say

16 this turned into Ultrapro, which was

17 available in 2003. So it is more the

18 historical perspective and at what time

19 points they knew that they needed

20 lighter-weight, larger-pore, less-stiff,

21 softer meshes.

22 THE COURT: He's already provided some

23 testimony to that.

24 MR. ANDERSON: That's right, Your

25

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1 Honor. I just want to show that this is a

2 side-by-side comparison so they can see how

3 much larger these holes are than this other

4 mesh and how much more dense that mesh is

5 than this mesh.

6 MR. CAMPBELL: So the reason why I

7 rose, and it was somewhat premature because

8 I did want to raise this issue to make sure

9 that we identified it, so that's why I rose

10 early. But I do believe that the testimony

11 from Dr. Rosenzweig has been in the plural,

12 meshes, safer alternative designs and the

13 meshes. I also believe that the question

14 that caused me to stand and object had to

15 do with safer alternative designs.

16 THE COURT: This witness is going to

17 be available to you for cross. I'm going

18 to overrule you at this point on this, and

19 I'd like to finish this testimony today. I

20 appreciate the fact that you're a little

21 premature. I get it. But let's go back.

22 I'm overruling this.

23 MR. CAMPBELL: If I could explore

24 then, if he says in the courtroom that

25

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Vypro is a safer alternative design, Your Honor, I have to object.

THE COURT: I can understand why you would at that point.

MR. ROSENBLATT: Your Honor, the way I heard the testimony, would you agree that Vypro and Ultrapro would be a safer alternative design?

THE COURT: When did you ask that question?

MR. ANDERSON: I don't remember asking that question.

THE COURT: Mr. Rosenblatt, when did you think that happened?

MR. ROSENBLATT: It was a little earlier on. I don't have the page and line, Your Honor. I'm sorry.

MR. ANDERSON: I'll go out there and say, what is this showing? It's showing a lighter-weight, larger-pore. Are you saying Vypro is a safer alternative design? No. What's a safer alternative design? Ultrapro. What was that? Next generation after Vypro. I can do that.

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MR. SNELL: That's totally within his report and testimony. I don't have an issue with that.

MR. ANDERSON: I'll just compare these two, and later on I'll ask him which one is safer. He'll say Ultrapro.

THE COURT: That's within his report.

(End of in camera proceedings.)

THE COURT: Mr. Anderson?

MR. ANDERSON: Thank you, Your Honor.

BY MR. ANDERSON:

Q. Let's go back to where we were.

Have you reviewed tab 49, P-1274?

A. Yes.

Q. Okay. And have you looked at a side-by-side comparison, at least as of the meshes that were available in 1998 in Ethicon's inventory, that would show a heavyweight, small-pore mesh next to a lightweight, large-pore mesh?

A. Yes.

MR. ANDERSON: If we could show that.

BY MR. ANDERSON:

Q. Okay. What are we seeing here on the left and the right, just in general terms?

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A. On the left-hand side is Vypro, which is a lighter-weight mesh. The pore size is approximately 3 to 5 millimeters. And then the Prolene mesh on the right side is about -- has a density of about 110 grams per meter squared and a pore size around a millimeter.

Q. After the Vypro mesh was on the market, did Ethicon develop another lightweight, large-pore mesh that would have been the second generation of these types of meshes?

A. Yes.

Q. What was the name of that device?

A. Ultrapro.

Q. Do you have an opinion as to whether Ultrapro would have been a safer alternative lightweight large-pore mesh than Prolene for the Secur device?

A. Yes.

Q. What is that opinion?

A. That Ultrapro would have been a safer alternative mesh than the Prolene mesh and the TVT Secur.

Q. And in general terms, why?

A. Because the lighter-weight mesh, the

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larger-pore mesh, creates less of a foreign body reaction, creates less inflammation, creates less fibrotic bridging, less scar plating, and less mesh contraction.

Q. Earlier we looked at the Klosterhalfen lightweight, large-pore concept article.

Do you recall that, Plaintiff's P-0791?

A. Yes.

Q. What opinions of yours with regard to lightweight large-pore meshes does that article support?

A. Well, first of all, that lightweight, large-pore mesh was available starting back in the late '90s, that there was less inflammation, less foreign body reaction, less scar plating, less mesh contraction with the lightweight, large-pore mesh, and, therefore, decreased the risk to patients of pain and mesh erosion and recurrence.

Q. Going to tab 50-1, Plaintiff's 2243, you mentioned Ethicon's consultants in Germany who helped them develop these less-stiff, softer meshes, Drs. Klinge and Klosterhalfen?

A. Yes.

Q. Have you reviewed other studies than them

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2 other than this lightweight, large-pore article
 3 related to complications from stiff meshes?
 4 A. Yes.
 5 Q. And what years were those studies by
 6 Ethicon consultants?
 7 A. 1998, 2002, and 2005.
 8 Q. Look at tab 50-1 and 50-2 being
 9 P-1454. Is this one of those articles?
 10 A. Yes.
 11 Q. And does this inform your opinions in this
 12 case?
 13 A. Yes.
 14 Q. Is it authoritative?
 15 A. Yes.
 16 Q. Is it something you relied on?
 17 A. Yes.
 18 Q. And then we also looked at P-2243. Is that
 19 something that you reviewed and relied upon in this
 20 case?
 21 A. Yes.
 22 Q. Are these the articles by Ethicon's
 23 consultants you were just referring to?
 24 A. Correct.
 25 Q. Just in general terms, what opinions of

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2 yours does this 1998, 2002, and the 2005 articles
 3 support by these consultants for Ethicon?
 4 A. That a lighter-weight, larger-pore mesh has
 5 less fibrosis, chronic foreign body reaction, chronic
 6 inflammation, leads to less scar plating, less
 7 contraction, which would cause less injuries to
 8 patients such as pain, erosion, and recurrence.
 9 Q. Thank you, Doctor.
 10 You mentioned Ultrapro. Did Ethicon ever
 11 incorporate this Ultrapro lightweight, large-pore
 12 mesh into implantable pelvic products?
 13 A. Yes.
 14 Q. What products did they incorporate them
 15 into?
 16 A. It was a product used to treat the prolapse
 17 that we talked about earlier this morning, when the
 18 support structures of the vagina become weakened, and
 19 this is used to support them. There was a product
 20 called Prolift+M. So it was a pelvic floor product
 21 to treat prolapse.
 22 Q. And based upon your review of the
 23 literature, your review of internal Ethicon
 24 documents, your review of the deposition testimony of
 25 Ethicon witnesses, as well as your own background,

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1 training, and experience, do you have an opinion as
 2 to whether or not the Ultrapro could have been used
 3 instead of the Prolene in the TVT Secur mesh?
 4 A. Yes.
 5 Q. What is that opinion?
 6 A. That if Ultrapro had been used instead of
 7 the Prolene mesh in the TVT Secur, it would have
 8 mitigated, decreased, or stopped completely the
 9 problems that we have been discussing of chronic
 10 foreign body reaction, scar plating, mesh
 11 contraction, which leads to pain, erosion, recurrence
 12 of urinary symptoms.
 13 Q. Doctor, who is Dr. Piet Hinoul?
 14 A. Dr. Piet Hinoul is a medical director,
 15 worldwide medical director at Ethicon.
 16 Q. Did you review his deposition testimony in
 17 this case?
 18 A. Yes, I did.
 19 Q. Did you review testimony of Dr. Piet
 20 Hinoul, the worldwide medical affairs director at
 21 Ethicon, regarding whether his opinion of
 22 lightweight, large-pore meshes would be softer in a
 23 woman's tissue?
 24 A. Yes.

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1 Q. What did he say?
 2 A. It would be softer in a woman's tissue.
 3 Q. Do you recall from his testimony whether or
 4 not he said that it could reduce pain in women?
 5 MR. CAMPBELL: Judge, I object. It's
 6 leading.
 7 THE COURT: Rephrase your question.
 8 BY MR. ANDERSON:
 9 Q. With your review of Dr. Hinoul's sworn
 10 deposition testimony, did he mention whether or not
 11 pain could or could not be related to heavyweight
 12 meshes?
 13 MR. CAMPBELL: Same objection, Your
 14 Honor.
 15 THE COURT: Overruled.
 16 THE WITNESS: Yes.
 17 BY MR. ANDERSON:
 18 Q. What did he say about the difference
 19 between heavyweight and lightweight meshes with
 20 regard to pain?
 21 A. That lightweight mesh decreases pain.
 22 Q. And was there any testimony one way or
 23 another as to how long Dr. Hinoul testified that his
 24 company knew about this?

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2 MR. CAMPBELL: Judge, I object.

3 THE COURT: Restate your question.

4 BY MR. ANDERSON:

5 Q. In your review of the testimony, the sworn

6 testimony of Ethicon's worldwide medical affairs

7 director, did you agree with or disagree with the

8 length of time that Ethicon may have known about

9 these products?

10 MR. CAMPBELL: Judge, I object.

11 THE COURT: Sustained.

12 BY MR. ANDERSON:

13 Q. How long did Dr. Hinoul know that Ethicon

14 had known about this?

15 MR. CAMPBELL: Judge, I object. It's

16 taken out of context. Dr. Hinoul is going

17 to testify, I believe, by deposition.

18 THE COURT: I'll permit this.

19 THE WITNESS: Since before the TVT

20 Secur was launched.

21 BY MR. ANDERSON:

22 Q. When was that?

23 A. In 2006, September 20.

24 Q. Turning now to Exhibit P-1842, to further

25 this discussion a little longer about the

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2 Q. What opinions of yours does this article

3 support in this case?

4 A. That Ultrapro can be used as a sling to

5 treat stress urinary incontinence. It is effective

6 and decreases complications.

7 Q. How long was this study?

8 A. It was four and a half years.

9 Q. Thank you. Do you have an opinion as to

10 whether or not, had Ethicon used the Ultrapro mesh in

11 its TVT Secur device, if it would have eliminated or

12 mitigated, lessened, the problems of chronic foreign

13 body reaction, chronic inflammation, and scar

14 plating?

15 A. Yes.

16 Q. What is that opinion?

17 A. It would have lessened or obviated the

18 chronic foreign body reaction, chronic inflammation,

19 and scarring.

20 Q. Do you have an opinion as to whether or not

21 the Ultrapro mesh, if used in the TVT Secur device,

22 would have lessened the multiple recurrent erosions,

23 the risk to patients of chronic pain, chronic vaginal

24 pain, and chronic urinary symptoms?

25 A. Yes.

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1 lightweight, large-pore Ultrapro mesh, that would be

2 tab 50-4.

3

4 THE COURT: P-1842 did you say?

5 MR. ANDERSON: Yes, Your Honor.

6 THE COURT: Thank you.

7 BY MR. ANDERSON:

8 Q. Is this something you reviewed in forming

9 your opinions in this case?

10 A. Yes.

11 Q. Is this article significant to your

12 opinions in this case?

13 A. Yes.

14 Q. Is it an authoritative text?

15 A. Yes.

16 Q. Okay. Please first explain what this was

17 in terms of its title and author. Then I'll ask you

18 if it supports your opinions.

19 A. Yes. It is from a Dr. Okulu from the

20 Scandinavian Journal of Urology in 2013. The title

21 is: Use of three types of synthetic material in

22 sling surgery: A prospective randomized clinical

23 trial evaluating effectiveness and complications.

24 Q. Was Ultrapro one of the meshes studied?

25 A. Yes.

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2 Q. What is that opinion?

3 A. It would have lessened the risk of chronic

4 erosions, recurrent erosions, chronic pain, and

5 urinary symptoms.

6 Q. Have you seen documents that we've either

7 looked at here today or deposition testimony that

8 would support the fact that stiff and rigid mesh

9 causes chronic long-term inflammation at or before

10 the first time?

11 MR. CAMPBELL: Objection.

12 MR. ANDERSON: Let me see if I can

13 rephrase it.

14 BY MR. ANDERSON:

15 Q. With regard to the documents that you've

16 reviewed here today, do they support your opinion in

17 this regard that the stiff and rigid mesh causes less

18 chronic long-term inflammation?

19 MR. CAMPBELL: Object. It's

20 cumulative at this point. It's also

21 leading.

22 THE COURT: I'm going to sustain the

23 objection as to the cumulative nature of

24 the testimony.

25 MR. ANDERSON: Okay. That's fine,

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2 Your Honor.
 3 BY MR. ANDERSON:
 4 Q. Do you have an opinion to a reasonable
 5 degree of medical certainty as to whether the stiff
 6 and rigid mesh increases the risk to patients of
 7 erosions, pain with sex, and urinary problems?
 8 MR. CAMPBELL: Same.
 9 THE COURT: Actually, this question is
 10 slightly different and I'll permit it.
 11 Overruled.
 12 THE WITNESS: Can you repeat the
 13 question, please?
 14 BY MR. ANDERSON:
 15 Q. Certainly. Do you have an opinion within a
 16 reasonable degree of medical certainty whether the
 17 stiff and rigid mesh in the TVT Secur increases the
 18 risk to patients of erosions, including multiple
 19 erosions, pain with sex, and urinary problems,
 20 including chronic urinary problems?
 21 A. Yes.
 22 Q. What is that opinion?
 23 A. That the rigid stiff mesh increases the
 24 risk of erosions, pain, and urinary problems.
 25 Q. And was the Ultrapro mesh commercially

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1 A. Yes.
 2 Q. And have you had personal experience with
 3 IFUs in your clinical practice?
 4 A. Yes, I have.
 5 Q. How many?
 6 A. Hundreds.
 7 Q. Okay. And do you have an opinion as to
 8 whether or not it is an important document for
 9 surgeons like yourself?
 10 A. Yes, it is.
 11 Q. Why?
 12 A. The instructions for use contain
 13 information for doctors about how to use the device,
 14 what patients they would be used for, what patients
 15 it should not be used for, what are the risks, what
 16 are the adverse events, and what are the warnings
 17 associated with the device.
 18 Q. Do you as a doctor rely on the manufacturer
 19 to inform you of all the risks and dangers of their
 20 products in the IFU?
 21 A. Yes.
 22 Q. Okay. Doctor, what is a risk-benefit
 23 analysis?
 24 A. Well, it's an analysis that one does, in

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2 available and economically feasible to be used to
 3 treat SUI at the time the Secur was launched in 2006?
 4 MR. CAMPBELL: I object. It's
 5 leading.
 6 THE COURT: Overrule that objection.
 7 THE WITNESS: Yes, it was.
 8 BY MR. ANDERSON:
 9 Q. Let me repeat the question.
 10 A. Thank you.
 11 Q. Was Ultrapro mesh commercially available
 12 and economically feasible to be used to treat stress
 13 urinary incontinence as of the time the Secur was
 14 launched in September of 2006?
 15 A. Yes, it was both commercially available and
 16 economically feasible in 2006.
 17 Q. Okay. Doctor, we talked earlier about the
 18 IFU briefly; correct?
 19 A. Yes.
 20 Q. Okay. I want to talk a little bit more
 21 specifically about it now.
 22 You mentioned they come with all medical
 23 devices; is that correct?
 24 A. That is correct.
 25 Q. Would that include the TVT Secur device?

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1 this case, myself as a doctor, when I am deciding on
 2 a treatment or a procedure for a patient. I gauge
 3 the risks of the procedure versus the benefits and
 4 utility for the patient.
 5 Q. And do you know what an informed consent
 6 is?
 7 A. Yes.
 8 Q. Can you please explain for the jury what an
 9 informed consent is and why it's important?
 10 A. Informed consent is a process that the
 11 doctor and the patient has whereby the doctor
 12 describes to the patient the procedure or treatment
 13 that he or she is recommending, what the benefits of
 14 that procedure or treatment is, what the alternatives
 15 are, and what the risks are so that the patient and
 16 the doctor together can make a decision, based on
 17 this information, whether or not this treatment or
 18 procedure is right for the individual patient.
 19 Q. Have you seen documents and testimony in
 20 this case that inform you of the standard that
 21 Ethicon uses for what needs to be in an IFU?
 22 A. Yes.
 23 Q. Have you reviewed the deposition testimony
 24 of Dr. Robinson?
 25

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<p style="text-align: right;">105</p> <p style="text-align: center;">DIRECT - ROSENZWEIG</p> <p>2 A. Yes.</p> <p>3 Q. Who is Dr. Robinson?</p> <p>4 A. Medical director at Ethicon.</p> <p>5 Q. A surgeon like you?</p> <p>6 A. Yes.</p> <p>7 Q. What type of surgeon?</p> <p>8 A. A gynecologic surgeon.</p> <p>9 Q. Were doctors and surgeons at Ethicon</p> <p>10 involved in drafting the warning labels at Ethicon?</p> <p>11 A. Yes.</p> <p>12 Q. Did you rely on Dr. Robinson's testimony in</p> <p>13 forming your opinions in this case?</p> <p>14 A. Yes.</p> <p>15 Q. Did you reasonably rely on Dr. Robinson's</p> <p>16 testimony to determine what Ethicon's internal</p> <p>17 guidelines were for what should be in these IFUs?</p> <p>18 A. Yes.</p> <p>19 Q. Was his testimony regarding what Ethicon's</p> <p>20 guidelines were significant to your opinions in this</p> <p>21 case?</p> <p>22 A. Yes.</p> <p>23 Q. What did Dr. Robinson testify to what the</p> <p>24 significant -- strike that.</p> <p>25 Based on your review of his testimony, what</p> <p style="text-align: center;">SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>	<p style="text-align: right;">106</p> <p style="text-align: center;">DIRECT - ROSENZWEIG</p> <p>2 were Ethicon's internal guidelines for what should be</p> <p>3 in an IFU?</p> <p>4 A. All significant risks and adverse events</p> <p>5 should be contained in the instructions for use.</p> <p>6 Q. Have you reviewed other documents and</p> <p>7 depositions regarding what Ethicon's internal</p> <p>8 requirements were for what needed to be in an IFU?</p> <p>9 A. Yes.</p> <p>10 Q. Who is Dr. Piet Hinoul?</p> <p>11 A. Worldwide medical director.</p> <p>12 Q. What of his deposition testimony, if any,</p> <p>13 informed you as to what should be included in an</p> <p>14 Ethicon IFU like the Secur?</p> <p>15 A. His deposition testimony?</p> <p>16 Q. Yes.</p> <p>17 A. He also stated that all known risks should</p> <p>18 be in the IFU, and the instructions for use should</p> <p>19 not downplay the significance or the propensity of</p> <p>20 risks that are associated with the device.</p> <p>21 Q. Per Ethicon's own internal guidelines as</p> <p>22 you've just mentioned, does the IFU for the Secur</p> <p>23 need to say anything about the mesh itself?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Why?</p> <p style="text-align: center;">SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>
<p style="text-align: right;">107</p> <p style="text-align: center;">DIRECT - ROSENZWEIG</p> <p>2 A. Well, the mesh itself is a characteristic</p> <p>3 of the device, and this character -- the instructions</p> <p>4 for use should describe all the characteristics of</p> <p>5 the device and the risks associated with that</p> <p>6 specific characteristic of the device.</p> <p>7 Q. What is your opinion regarding the adequacy</p> <p>8 of the warnings in this IFU for the Secur?</p> <p>9 A. The adequacy of the warnings is not</p> <p>10 sufficient in the IFU.</p> <p>11 Q. Why is that?</p> <p>12 A. Because there are a number of warnings in</p> <p>13 the instructions for use that are not contained in</p> <p>14 the instructions for use.</p> <p>15 Q. With my assistance, did you prepare slides</p> <p>16 that would contain your opinions as to what warnings</p> <p>17 should have been in the IFU for the TVT Secur?</p> <p>18 A. Yes.</p> <p>19 Q. Are those approximately six slides?</p> <p>20 A. Yes, sir.</p> <p>21 MR. CAMPBELL: Your Honor, again, I</p> <p>22 object.</p> <p>23 THE COURT: Basis of your objection?</p> <p>24 MR. CAMPBELL: It will produce a</p> <p>25 leading response. He should be asked his</p> <p style="text-align: center;">SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>	<p style="text-align: right;">108</p> <p style="text-align: center;">DIRECT - ROSENZWEIG</p> <p>2 opinions as to what the warnings should be.</p> <p>3 THE COURT: I'm going to permit this</p> <p>4 to be introduced, and if you have an</p> <p>5 objection as to going forward, please</p> <p>6 present it at that time.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. With regard to the first warning</p> <p>9 requirement that you believe should have been in the</p> <p>10 IFU, could you publish that?</p> <p>11 A. The warning about foreign body reaction,</p> <p>12 inflammatory reaction.</p> <p>13 Q. What do you believe that warning should</p> <p>14 have said, Doctor?</p> <p>15 A. The TVT Secur has a chronic foreign body</p> <p>16 reaction and chronic --</p> <p>17 Q. A little slower for her.</p> <p>18 A. -- inflammatory response in vaginal tissue</p> <p>19 that persists over the life of the product. This can</p> <p>20 lead to excessive scarring causing the mesh to become</p> <p>21 encapsulated in scar and to contract or shrink the</p> <p>22 mesh up to an area of 50 percent. This can cause</p> <p>23 chronic recurrent erosions, chronic pain,</p> <p>24 dyspareunia, and chronic urinary dysfunction.</p> <p>25 Q. Is this warning in the Secur IFU?</p> <p style="text-align: center;">SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014</p>

2 A. No.

3 Q. Do you have an opinion whether doctors like

4 yourself would have liked to have this warning in the

5 device?

6 MR. CAMPBELL: Excuse me, Judge. I

7 object to the form of that question.

8 THE COURT: Please restate your

9 question.

10 MR. ANDERSON: Sure.

11 BY MR. ANDERSON:

12 Q. As a doctor who is deciding whether to

13 implant medical devices, would this warning have been

14 significant to you?

15 MR. CAMPBELL: Objection. That's

16 irrelevant.

17 THE COURT: I'm going to permit the

18 question. Overruled.

19 THE WITNESS: Yes. This would be an

20 important warning for me to know prior to

21 having a discussion with my patient

22 regarding a treatment such as the Secur.

23 BY MR. ANDERSON:

24 Q. Let's go to slide two, if we could. What

25 is slide two? Can you explain that to the jury?

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2 A. This is a warning regarding heavyweight,

3 small-pore mesh. The mesh in the Secur is

4 heavyweight, small-pore mesh. Heavyweight,

5 small-pore mesh increases the risk of multiple

6 recurrent erosions and mesh exposure, chronic pain,

7 chronic dyspareunia, and chronic urinary dysfunction,

8 including frequency, urgency, and recurrent urinary

9 tract infections.

10 Q. Was this warning or anything like it in the

11 TVT Secur IFU?

12 A. No.

13 Q. As a surgeon deciding whether to implant a

14 medical device, would this be important to you in

15 your practice?

16 A. Yes.

17 Q. Why?

18 A. Because this is information that I would

19 want to know to be able to discuss this with my

20 patient when doing the informed consent process.

21 Q. Did the IFU for Secur say it was a

22 heavyweight, small-pore mesh?

23 A. No.

24 Q. Did it say it increased the risk of

25 multiple recurrent erosions?

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1 A. No.

2 Q. Did it say it increased the risk of chronic

3 pain?

4 A. No.

5 Q. Did it even mention chronic dyspareunia?

6 A. No.

7 Q. Let's go to the third slide, please.

8 A. Warning regarding stiffness. The TVT Secur

9 is more rigid and stiff than mesh used in other TVT

10 products. Stiff or rigid mesh increases the risk of

11 multiple recurrent erosions and mesh exposure,

12 chronic pain, including chronic dyspareunia, chronic

13 urinary dysfunction, including urgency, frequency,

14 and recurrent urinary tract infections.

15 Q. Was this in the TVT Secur or anything like

16 this in the TVT Secur IFU?

17 A. No.

18 Q. As a doctor who is trying to decide whether

19 to implant a medical device, would this have been

20 important to you in your practice?

21 A. Yes.

22 Q. Go to the next slide. In terms of this

23 warning that you believe should have been in the

24 Secur, please explain it.

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1 A. The Secur uses a sharp introducer tool.

2 The sharp introducer tool increases the risk of

3 multiple recurrent erosions and mesh exposure,

4 chronic pain, including chronic dyspareunia, chronic

5 urinary dysfunction, including urgency, frequency,

6 and recurrent urinary tract infections.

7 Q. Does the IFU for the TVT Secur talk at all

8 about the tissue damage that could be caused by these

9 sharp tools and lead to chronic issues for a woman?

10 A. No.

11 Q. Was there anything like this that was

12 included in the TVT Secur IFU?

13 A. No.

14 Q. As a doctor trying to decide with a patient

15 whether or not to implant the device, would this be

16 significant to you in your practice?

17 A. Yes.

18 Q. Go to the next slide, please. Can you

19 explain why you believe or explain what you believe

20 should have been in with regard to this warning?

21 A. The TVT Secur uses absorbable fleece tips

22 to hold the mesh in place. Because of this, the

23 fleece tips can cause the mesh to move or migrate

24 after being placed in the body. The movement of the

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2 stiff and rigid mesh increases the risk of multiple
 3 recurrent erosions and mesh exposure, chronic pain,
 4 including chronic dyspareunia, chronic urinary
 5 dysfunction, including urgency, frequency, and
 6 recurrent urinary tract infections.
 7 Q. Did this appear in the TVT Secur IFU?
 8 A. No.
 9 Q. Was there anything about the fleece tips
 10 moving and migrating in the tissue after the woman
 11 was sewn up, anything about that in the Secur
 12 warning?
 13 A. No.
 14 Q. Would you as a doctor trying to decide
 15 whether or not to implant a medical device
 16 permanently in a woman's vagina have wanted to know
 17 this type of information?
 18 A. Yes.
 19 Q. Go to the next slide, please. Why do you
 20 have this as a warning that you believe should have
 21 been included in the Secur or something like it?
 22 A. Because the design features of the Secur
 23 device were not adequately studied in women prior to
 24 being sold. The device was only studied in sheep and
 25 cadavers. The initial results of the Secur have

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2 shown inferior patient outcomes compared to other
 3 devices.
 4 Q. Was this included in the TVT Secur?
 5 A. No.
 6 Q. Do you believe it should have been?
 7 A. Yes.
 8 Q. Do you believe all of these should have
 9 been included?
 10 A. Yes.
 11 Q. As a doctor, would you have liked to have
 12 known that the Secur was only studied in sheep,
 13 cadavers, and a few women at the time it was
 14 launched?
 15 A. Yes.
 16 MR. ANDERSON: This is a good time.
 17 THE COURT: I think this might be an
 18 appropriate time. Thank you very much.
 19 Doctor, you may step down.
 20 THE WITNESS: Thank you.
 21 (The witness exits the stand.)
 22 THE COURT: Members of our jury, as
 23 you prepare to take a three-day break from
 24 our trial, I'd like you to remember a few
 25 things. First, if you recall, when we

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1 COLLOQUY
 2 first spoke, I said you can't make any
 3 decisions until you have all of the
 4 evidence, and that's going to be another
 5 several days. So I'm going to caution you
 6 not to think about this case in terms of
 7 what you've already heard knowing that you
 8 haven't heard everything. Two sides to
 9 every story.
 10 Second, I want to remind you that it's
 11 not advisable to really talk about this
 12 case with anybody. Generally, people will
 13 not be very positive about their own
 14 experiences with jury duty, and I don't
 15 want that to affect your own perceptions.
 16 And third, you cannot do any research
 17 or in any way seek any information
 18 whatsoever about the matters that we are
 19 discussing in this room. To do so will
 20 prejudice the trial and can significantly
 21 affect having a fair and impartial case,
 22 which is what we're all here about.
 23 Fourth, eat a lot. It's one of those
 24 weekends where we get to, a lot of us, and
 25 don't ever pass up that opportunity,

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1 COLLOQUY
 2 especially for the egg.
 3 So you are a great jury. We're very
 4 grateful to you. We understand it's not an
 5 easy trial, but I don't think I've ever
 6 known an easy trial on jurors. Thank you
 7 very much. I'm going to ask everyone to
 8 rise while the jury leaves the room.
 9 (The jury exits the courtroom at
 10 3:29 p.m.)
 11 THE COURT: Anything that we need to
 12 put on the record?
 13 MR. ANDERSON: No.
 14 MR. HIGGINBOTHAM: Your Honor, Daniel
 15 Higginbotham for the defendants. Would it
 16 be okay if I put on the record our
 17 discussions this morning about the FDA
 18 statement?
 19 THE COURT: Yes.
 20 MR. HIGGINBOTHAM: Your Honor, as you
 21 recall, one day this week, you granted
 22 Plaintiff's Motion in Limine No. 6, I
 23 believe it was, to exclude evidence of the
 24 FDA 510(k) and the advisory committee's
 25 statements. You also suggested to the

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2 parties that we prepare a joint statement
 3 regarding the FDA. The defendants have
 4 done so, and if I can mark as a court
 5 exhibit our proposal.

6 THE COURT: You may.

7 MR. HIGGINBOTHAM: May I approach to
 8 hand it to Your Honor?

9 THE COURT: You may.

10 MR. HIGGINBOTHAM: How will that be
 11 marked, Your Honor?

12 THE COURT: We're going to mark it
 13 Court Exhibit A Defense.

14 MR. HIGGINBOTHAM: Court Exhibit A
 15 entitled "Defendant's proposed statement
 16 regarding FDA evidence," again, is
 17 submitted in response to Your Honor's
 18 directive that we provide some guidance to
 19 the jury about the FDA.

20 Defendants don't intend to submit that
 21 statement as a replacement for FDA
 22 evidence. We still believe that evidence
 23 is relevant and necessary but understand
 24 Your Honor's ruling on that point.

25 We also wanted to make it clear for

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1 COLLOQUY

2 affirmed the trial court, Judge Goodwin,
 3 the MDL judge, keeping out the FDA in its
 4 entirety on 403 as opposed to 402 because
 5 of its prejudice.

6 In addition to the opening statements
 7 made by both parties that were good and
 8 thorough and I think the depth and breadth
 9 of the plaintiff's opening statement in
 10 this case, I don't think any juror that
 11 thought the FDA did not approve its product
 12 would have a doubt. That would have been
 13 mentioned had it been true. Once the FDA
 14 comes in, if you're in for a penny, you're
 15 in for a pound, and it should stay out in
 16 its entirety.

17 THE COURT: Thank you. The Court
 18 notes that when I discussed this matter
 19 with counsel today, there was a
 20 reconsideration by the Court as to the
 21 advisability including a statement
 22 regarding the FDA.

23 I believe that having a statement
 24 regarding the FDA read to the jury at this
 25 time would be inconsistent with the ruling

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2 the record that we're submitting that
 3 statement for purposes of this case only
 4 and certainly reserve our right in other
 5 cases, both in Philadelphia and other
 6 jurisdictions, to seek admission of FDA
 7 evidence, Your Honor.

8 We talked this morning briefly about
 9 why we think that statement should be read.
 10 We think it should be read because the jury
 11 comes in understanding that these products
 12 are subject to regulation. We think that
 13 reminding the jury that the FDA is out
 14 there, that the TVT Secur was lawfully
 15 marketed from 2006 to 2012, and reminding
 16 the jury that they are not to speculate
 17 about what the FDA did or did not do is
 18 important to guard against the risk of
 19 unfair speculation on the part of the
 20 jurors as to what the FDA did.

21 THE COURT: Any response?

22 MR. BRADFORD: Brad Bradford for the
 23 plaintiff. We spoke about this this
 24 morning, Your Honor. The 4th Circuit
 25 opinion regarding the Bard MDL trial, they

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1 COLLOQUY

2 that I made in I believe it was Plaintiff's
 3 Motion in Limine No. 6.

4 MR. HIGGINBOTHAM: That's correct,
 5 Your Honor.

6 THE COURT: Accordingly, there will
 7 not be any statement read to the jury with
 8 regards to the FDA.

9 MR. BRADFORD: That's a nice memory
 10 you have there.

11 MR. HIGGINBOTHAM: Thank you, Your
 12 Honor.

13 MR. BRADFORD: The only other issue,
 14 this weekend I'll be working on
 15 Dr. Bolton's deposition transcript. We had
 16 mentioned publishing your ruling. Both
 17 sides have good notes. I think publishing
 18 might be as easy as however you think would
 19 be the best way just to provide us with a
 20 copy of your notes to make sure ours match
 21 each other's and yours. That's how I would
 22 recommend doing it, if you're so inclined.

23 THE COURT: I think we should be able
 24 to do that before you leave. We'll get
 25 copies of that immediately. You can take a

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look at them over the weekend.
For those people who are traveling, I
hope you get to the airport quickly. I
will be here at 8:00 on Monday morning if
anybody wishes to speak about anything.
(Proceedings adjourned.)

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CERTIFICATE

I, Shannan Gagliardi,
Registered Diplomate Reporter in and for the
Commonwealth of Pennsylvania, do hereby certify that
the foregoing is a true and accurate transcript of
the notes of testimony of said witness who was first
duly sworn on the date and place hereinbefore set
forth.

I further certify that I am
neither attorney nor counsel for, nor related to or
employed by any of the parties to the action in which
this trial was taken, and further, that I am not a
relative or employee of any attorney or counsel
employed in this action, nor am I financially
interested in this case.

SHANNAN GAGLIARDI
Registered Diplomate Reporter
Certified Realtime Reporter